15-2411-cv

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CHURCH & DWIGHT CO., INC., a Delaware corporation,

Plaintiff-Appellee,

v.

SPD SWISS PRECISION DIAGNOSTICS GmbH, a Swiss Corporation,

Defendant-Appellant.

On Appeal from the United States District Court
for the Southern District of New York, No. 14-cv-585
Before the Honorable Alison J. Nathan

BRIEF FOR DEFENDANT-APPELLANT
SPD SWISS PRECISION DIAGNOSTICS GMBH

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CORPORATE DISCLOSURE STATEMENT

SPD Swiss Precision Diagnostics GmbH is owned by Alere Switzerland GmbH and Procter & Gamble International Operations SA. Alere Switzerland GmbH is an indirect subsidiary of Alere Inc. Alere Inc. has no parent corporation, and no publicly held corporation owns 10% or more of its common stock. Procter & Gamble International Operations SA is an indirect subsidiary of The Procter & Gamble Company. The Procter & Gamble Company has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

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INTRODUCTION

This appeal challenges a sweeping Lanham Act injunction that conflicts with requirements imposed by the Food and Drug Administration, enjoins truthful speech based on a flawed Lanham Act analysis, and imposes draconian mandates that go far beyond the purported harm in this case.

At the heart of the case is SPD Swiss Precision Diagnostics GmbH's novel home pregnancy test —the "Clearblue Advanced Pregnancy Test with Weeks Estimator"—that informs a woman whether she is pregnant and estimates the number of weeks that have passed since ovulation. Church & Dwight Co., Inc., which manufactures competing home pregnancy tests without the innovative "Weeks Estimator" feature, challenged the labeling and promotion of SPD's product as false and misleading under the Lanham Act. C&D argued that doctors have historically expressed the length of pregnancy by reference to a woman's last menstrual period ("LMP"), approximately two weeks *before* ovulation and conception, and that consumers were allegedly deceived into thinking SPD's estimate was the same as a doctor's.

The district court accepted C&D's theory in part and held that SPD violated the Lanham Act because its labeling and promotion—indeed, the very FDA-mandated name of its product—allegedly conveyed the message that the product's estimate of "weeks" is the same as a doctor's. Based on this conclusion, the

district court entered an extraordinary injunction that includes, among other things, a nationwide recall of the product, a prohibition against SPD using the FDA-mandated name, detailed requirements for future packaging that cannot be implemented without FDA approval, and an extensive campaign of forced speech branding SPD as a false advertiser.

This injunction, and the Lanham Act ruling on which it is based, should be reversed. *First*, C&D's Lanham Act claim is precluded because it conflicts with requirements imposed by the FDA as part of its detailed control of SPD's labeling and promotion. This was no ordinary approval process. The FDA invoked its extraordinary and rarely used authority under Section 513 of the Food Drug and Cosmetic Act to dictate critical elements of SPD's materials, including the name of the product and a description of what the product does and does not do. In response to complaints from C&D, the FDA then expanded on these requirements and reiterated that SPD could not deviate from them. The district court improperly ignored these FDA-imposed restrictions on SPD's ability to unilaterally change of its materials. Indeed, the district court's injunction crystalizes the conflict by ordering actions SPD cannot take without FDA approval. Under controlling Supreme Court precedent, C&D's claims are precluded.

Second, the district court's Lanham Act analysis was fundamentally flawed in multiple respects. SPD's revised packaging truthfully states that it "Estimates

Weeks Since Ovulation," but the district court improperly relied on survey evidence to override the plain meaning of this statement, and then compounded the error by ignoring substantial flaws in the survey's methodology. The court also misapplied the literal falsity analysis, strained to find intent to deceive, and relied on the same flawed survey with respect to SPD's labeling and marketing in the launch period. Throughout, the district court's findings of materiality and injury relied on the impact of the "weeks estimator" feature without proof that the allegedly *false advertising* relating to that feature impacted purchase decisions and caused C&D competitive harm.

Third, the injunction is vastly disproportionate to the purported harm to be remedied. It enjoins advertising for which the district court expressly found there was no evidence of consumer confusion, it mandates unnecessarily inflammatory language branding SPD as a false advertiser, and its scope far exceeds any purported harm.

The district court's injunction and underlying finding of liability should be reversed or, at a minimum, vacated.

STATEMENT OF JURISDICTION

The district court had jurisdiction over C&D's Lanham Act claim under 28 U.S.C. § 1331. On July 1, 2015, the district court held that SPD violated the Lanham Act and announced the contours of an injunction against SPD. SPA1-54.

On July 30, 2015, SPD filed a timely notice of interlocutory appeal. JA1390-1391. On August 26, 2015, the district court entered a permanent injunction against SPD. SPA55-61. On September 4, 2015, SPD filed a timely amended notice of interlocutory appeal. JA1412-1414. This Court has jurisdiction over the appeal under 28 U.S.C. § 1292(a)(1).

STATEMENT OF ISSUES ON APPEAL

1. Whether C&D's Lanham Act claim and the district court's injunction are precluded by the FDA's exercise of its authority under 21 U.S.C § 360c(i)(1)(E).

2. Whether the district court's ruling on SPD's revised materials should be reversed because it (a) improperly relied on survey evidence to override the plain meaning of SPD's message, and (b) ignored fundamental flaws in C&D's consumer survey.

3. Whether the district court's ruling on SPD's launch-period materials should be reversed because it (a) applied an erroneous literal falsity analysis; (b) improperly applied an intent-based presumption of consumer confusion; and (c) ignored fundamental flaws in C&D's consumer survey.

4. Whether the district court's analysis of materiality and injury to C&D improperly failed to determine that the allegedly false message impacted purchase decisions and caused a likelihood of competitive harm.

5. Whether the district court's injunction should be reversed or, in the alternative, vacated because it enjoins materials never found to be false or misleading and is vastly disproportionate to the purported harm it seeks to address.

STATEMENT OF FACTS

A. SPD's Weeks Estimator

SPD is a leading global supplier of home pregnancy and fertility-related products, which are sold under the brand name CLEARBLUE®. JA967; JA1591. C&D is also a leading supplier of home pregnancy tests, which are sold under the brand name FIRST RESPONSE®. JA967.

Home pregnancy tests, including SPD's and C&D's tests, determine whether a woman is pregnant by detecting or failing to detect the presence of human chorionic gonadotropin ("hCG") in a woman's urine. The product at issue in this case—SPD's "Clearblue Advanced Pregnancy Test with Weeks Estimator"—is a unique, scientifically advanced test that, in addition to indicating whether a woman is pregnant, estimates how many weeks have passed since a pregnant woman ovulated (i.e., when an egg was released from her ovary). JA1592. The Weeks Estimator does this by measuring the hCG in the pregnant woman's urine and using that measurement to estimate when ovulation occurred. Because fertilization of the egg must occur within 24 hours of ovulation, the estimate of weeks since

ovulation provides an estimate of weeks since conception (i.e., weeks since the biological start of pregnancy). JA1592-1593.

SPD's product has been launched in more than 30 countries since July 2008, when it was first put on the market in the UK and Ireland. JA1591-1592; JA1758. More than 31 million test kits had been sold globally as of June 30, 2014. JA1592; JA1761-1762. SPD's product is the only home pregnancy test in the U.S. market with a feature that estimates weeks. Competing home pregnancy tests, including C&D's, do not provide this information to women.

B. FDA Review Process

In 2008, SPD submitted a "510(k) application" to the Food and Drug Administration seeking clearance to market its product as a Class II medical device. The FDA review process was unusually intensive, and the FDA invoked its rarely used authority under Section 513(i)(1)(E) of the Food Drug and Cosmetic Act (codified at 21 U.S.C § 360c(i)(1)(E)) to exercise extensive control over SPD's labeling and promotional materials. Under that authority, the FDA approved or outright mandated critical elements of SPD's materials—from the name of its product, to the FDA-drafted "indications for use" on the side of the box, to numerous other details.

Section 513 empowers the FDA to require changes to labeling and promotional materials if it determines that there is a potential risk of harm from

off-label use that can be prevented with appropriate labeling. 21 U.S.C. § 360c(i)(1)(E). Unlike the normal 510(k) approval process, which leads to a "substantial equivalence" determination, a product approved under Section 513 receives a "substantial equivalence with limitations" or "SE with limitations" letter in which the FDA imposes specific restrictions on the product's labeling and promotion. *See, e.g.*, JA1594.

The FDA invoked Section 513 here to address the risk that a user "may misinterpret the weeks results to be a substitution for gestational age determination" by healthcare professionals—a determination that, by convention, is usually made using the LMP metric and through ultrasound. JA7581. Determining that this risk "may be prevented given adequate device labeling," the FDA issued a formal Hold Letter on September 12, 2012, which continued and intensified its control over SPD's messaging. JA7579-7589.

For example, SPD's initial application proposed calling its product the "Clearblue Advanced Pregnancy Test with *Conception Indicator*," JA9004.21 (emphasis added); JA9004.27; JA9680; *see also* SPA99-100, a name that SPD had used in other countries, JA1759. SPD also proposed that, as it had done abroad, the product include a conversion chart on the *outside* of the box comparing the product's estimate of "weeks" to the information a doctor might provide using the LMP convention. JA1595-1596; JA2317. The FDA, however, required SPD to

use a different name (ultimately, Clearblue® Advanced Pregnancy Test with Weeks Estimator) and to include the conversion chart only in the leaflet *inside* the package. JA3368-3372; JA1599.[1]

The FDA also drafted a detailed "indications for use" statement that it required SPD to include on the outside of its package:

> The Clearblue® Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).
>
> This test is only intended for individual use at home. It is not intended for use in a healthcare setting.
>
> This test contains a "Weeks Estimator." The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. The 'Weeks Estimator' is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.
>
> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor may determine how many weeks pregnant you are based on the first day of your last

[1] The district court said "it is not at all clear … that the FDA intended to prohibit SPD from including the conversion chart on the outside of the box." SPA 26. But the FDA's clearance letter states that "[p]erformance of the Weeks Estimator should not be displayed on your box labeling," which should instead direct users to the package insert. JA3368. In the next numbered paragraph, entitled "Package Insert," the FDA made clear what it meant by "performance": "Weeks Estimator *performance* should *only* be expressed as follows," after which the FDA displayed the conversion chart and three bullet points of data. JA3368-3369 (emphasis added). The FDA thus not only prohibited use of the chart on the box, but incorporated the prohibition into the binding "limitations" on marketing the product.

> menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

JA3370. It is undisputed that SPD has always included the FDA-mandated indications for use on the side of its product packaging.

The FDA also provided detailed directions concerning other elements of SPD's materials, from specific terminology, to placement, to font color. JA1599-1600; JA1996-2096. On November 27, 2012, FDA confirmed that the labeling and other materials prepared and submitted by SPD complied with its instructions and told SPD to prepare a formal response to the Hold Letter with the approved final labeling. JA1600-1601; JA2093-2096; JA2127-2130.

On December 10, 2012, the FDA issued a Clearance Letter for the product. JA3368-3371. Among other things, the letter reiterated that "the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling." JA3370.

C. Marketing of the Weeks Estimator

SPD launched its product in the United States nine months later, in August 2013. In the lengthy period between approval and launch, SPD made certain changes that it had been weighing for some time to better align the product's

package with global brand standards. JA1602. Most of these involved font styles and colors. In addition, instead of depicting two product display windows below the FDA-approved words "weeks along"—one showing "Pregnant" with "1-2" below it in the window, and one showing "Not Pregnant"—the updated package depicted four windows: "Pregnant" with "1-2 weeks" below it in the window, "Pregnant" with "2-3 weeks" below it, "Pregnant" with "3+ weeks" below it, and "Not Pregnant." JA1602-1603; *compare* JA2150, *with* JA2188-2189. This reflected the four possible results that the Weeks Estimator could return. SPD did not seek FDA clearance for these changes because it believed at the time that they were minor and consistent with what the FDA had approved. JA1603; JA9499-9502. SPD did not make any changes to the "indications for use," product name, or placement of the conversion chart.

SPD marketed the "Weeks Estimator" through a variety of channels. One feature of the campaign was a national television commercial that ran from August 28, 2013 to December 2, 2013. The commercial showed two women at a kitchen table saying the following:

First woman:	I'm pregnant
Second woman:	Really?
First woman:	Two weeks.
Second woman:	You already went to a doctor?
First woman:	Not yet, but I took this new Clearblue test. It's like two tests in one.

Second woman: Oh my God, I think I'm going to cry!

JA3384-3385. For two of the fifteen seconds of the commercial, the words "ESTIMATED WEEKS SINCE OVULATION" appeared on screen, and for nine of the fifteen seconds, a statement at the bottom of the screen said:

> Word 'weeks' on display is for illustration only. For home use only. Always consult a doctor if you suspect you are pregnant and to confirm, date and monitor pregnancy. Not for multiple pregnancies. Estimates weeks since ovulation up to 3+ weeks. Do not use to monitor pregnancy progress or duration.

JA3384; SPA14.[2]

D. Further FDA Review

Before filing suit, C&D complained to the FDA that certain aspects of SPD's labeling and promotion were deceptive and violated the conditions of the FDA's clearance. JA1603-1604; JA1581; JA2319-2400. The complaint mirrored the theories C&D advanced in this lawsuit.

In November 2013, SPD received an email from the FDA, stating that "[i]t has come to our attention that SPD is marketing the 'Clearblue Advanced Pregnancy Test with Week Estimator' device in violation of the limitations in FDA's clearance letter." The FDA requested a teleconference "to communicate

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[2] SPD used this shortened statement in light of correspondence with the FDA about the difficulty of reproducing the full "indications for use" in certain media, in which the FDA amended the Clearance Letter to state that the limitations needed to be "conveyed accurately"—but not necessarily "displayed"—in promotional materials. JA9004.6; *see also* JA3370; JA2162-2163.

our concerns and receive further clarifications." JA1604; JA2152; JA1582. SPD expressed surprise and concern. JA1604; JA2153-2156; JA1582.

On November 18, 2013, SPD and FDA representatives held a teleconference in which the FDA relayed its concerns about certain advertising for the Weeks Estimator. With respect to the carton, FDA officials expressed concern about the insertion of the word "weeks" in the depicted display window, and indicated that it should be removed and replaced with the words "weeks along" outside the window, as the FDA had originally approved. JA2160-2161. The FDA also questioned the change from the depiction of two display windows to four. SPD explained that this allowed the consumer to see all four possible results, making clear that the weeks estimate stops at "3+" weeks. The FDA approved this change.

With respect to the television commercial, the FDA expressed the additional concern that some dialogue might imply that the commercial's subject might be using the Weeks Estimator in lieu of medical care. JA1605; JA1583. The FDA also objected to the use of a shortened form of the "indications for use" in the commercial.

Between November 2013 and January 2014, SPD developed a "Mitigation Plan" to address these and other concerns raised by the FDA—touching on everything from advertising scripts to font sizes. JA1606-JA1610; JA2157-2177; JA1584-1588. At the FDA's direction, SPD stopped airing the TV Commercial

and replaced it with a modified Internet-Only Commercial that the FDA reviewed and approved. JA1587, JA2208, JA2216.[3] SPD also revised the front of its package to add the statement "Only Test That Estimates Weeks Since Ovulation*" on both main panels of the package. JA3380-3381. The asterisk directed women to the side of the box, which had always included the full "indications for use" drafted by the FDA.

After additional communications, SPD sent its Revised Package to FDA for approval on December 5, 2013. JA2185-2193. FDA responded: "The newly proposed carton box label is acceptable except the asterisk in front of your [indications for use] is too small. If you change it to a bit larger size to make it more visible, it will be acceptable." JA2194. SPD made the revision, JA2197, and the FDA responded: "The carton box design is acceptable now," JA2203. On February 3, 2014, SPD began shipping the product in the Revised Package. JA1587.

E. Procedural History

On January 29, 2014, C&D brought suit against SPD, asserting claims for false advertising under Section 43(a) of the Lanham Act and New York General

[3] The main differences between the Internet-Only Commercial and the original commercial were the omission of the dialogue about going to the doctor and the inclusion of the full indications for use at the conclusion of the commercial.

Business Law § 349 and for breach of contract.[4] On May 22, 2014, SPD moved to dismiss the complaint on grounds of preclusion under the Food Drug and Cosmetic Act. JA13. The district court denied that motion without prejudice to renewing it on a more developed record. JA146-160. On February 9, 2015, SPD re-raised its preclusion argument in a pre-trial motion. JA38. On March 24, 2015, the district court denied SPD's motion and held that C&D's false advertising claims were not precluded. JA1141-1160.

In April 2015, the district court held a two-week bench trial. The court accepted direct and rebuttal testimony in the form of affidavits, with live cross-examination held at trial. On July 1, 2015, the court found SPD liable for false advertising under the Lanham Act and New York state law.[5] SPA1-50. The court found that the advertising in connection with the product's launch (the "Launch Advertising"), including the product's package (the "Launch Package"), was literally false because the product necessarily implied the false message that the product's estimate was the same as a doctor's estimate of pregnancy. SPA29-32; SPA37-38. The court found, in the alternative, that SPD "intentionally set out to

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[4] The district court found no merit to C&D's breach of contract claim, SPA53, which is not at issue here.

[5] The parties agreed that Section 349 of New York's General Business Law is governed by the same standards as the Lanham Act, SPA28 n.14; thus, the substance of this appeal applies equally to C&D's New York General Business Law claim.

deceive consumers," giving rise to "a presumption 'that consumers, are, in fact, being deceived.'" SPA33; SPA38-40. Finally, as to the Launch Package, the district court relied on the results of a consumer survey conducted by C&D's expert, Hal Poret, to conclude that the Launch Package was likely to cause consumer confusion. SPA34-35. As for the revised materials, the court analyzed only the product's package and, relying on the Poret survey, found that the Revised Package was also likely to cause consumer confusion. SPA36-37. Finally, the district court found that C&D was entitled to a permanent injunction. SPA49-50.

On August 26, 2015, the district court entered a far-reaching permanent injunction that required SPD to undertake the following measures:

- *Immediately* institute a nationwide recall, SPA57;
- Cease using the FDA-approved name of the product, SPA57;
- Remove *any* depictions of the digital result windows—which were approved by the FDA and accurately show what the product displays—from all materials, SPA56-57.
- Remove from all materials certain language that was specifically approved by the FDA, SPA56-57;
- Within seven days, issue to all of its customers—including retailers, ecommerce websites, brokers, distributors, wholesalers, importers and others—"Corrective Notices" that state, among other things, that SPD has been found liable for false and misleading advertising, SPA57-58;

- Within seven days and for a period of one year, maintain a prominent, stand-alone page on its website with the Corrective Notice informing the public that SPD has been found liable for false and misleading advertising, SPA58-59;

- For a period of one year, any time it attends trade shows, provide the same notice to health care professionals (a group for whom there was no showing of confusion at trial and any misperception is unlikely), SPA58;

- "As expeditiously as possible," publish retail circulars, internet banner advertising, and full page magazine ads informing the public that SPD was found liable of false and misleading advertising, SPA59-60;

- Within 30 days, produce a video that must open with "In July 2015, a federal court found the manufacturer of the Clearblue® Advanced Pregnancy Test with Weeks Estimator to have engaged in false advertising ….", and run the video prominently on its web page for a full year, and on YouTube and Facebook for six months, SPA60; and

- Include a court-drafted "Clarification Statement" in any advertising for the product promoting the "weeks estimating" feature, in a font size and manner also mandated by the court, SPA56.

Immediately after issuing the injunction, the district court denied SPD's motion to stay the injunction pending appeal. JA1401-1411. SPD appealed and filed an emergency motion for a stay. Dkt. 33. This Court granted an administrative stay on September 1, 2015. Dkt. 47. SPD's stay motion was argued

on September 15, 2015. On September 17, 2015, a motions panel of this Court granted SPD's motion for a stay of the injunction pending appeal and ordered expedited briefing. Dkt. 71.

SUMMARY OF ARGUMENT

The district court's indiscriminate and overbroad Lanham Act injunction must be vacated, and the underlying liability determination reversed, for multiple reasons.

First, both the liability ruling and the injunction are premised on statements that were required by the FDA in its considered judgment and that SPD could not and cannot amend without FDA approval. SPD wanted to market the product as the "Conception Indicator" and to include on its box a chart comparing the Week's Estimator's results to the LMP method traditionally used by doctors. But the FDA exercised a rarely-invoked and sweeping form of authority to require a different name, dictate core aspects of SPD's labeling, and ultimately require that virtually all marketing receive its approval. Where, as here, Lanham Act liability cannot be avoided without receiving discretionary FDA approval, preclusion is required under the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Even if liability were not precluded, *PLIVA* requires that the injunction, most if not all of which is directly contrary to FDA dictates, be vacated.

Second, the district court's Lanham Act analysis is riddled with errors. The Weeks Estimator's revised packaging, which states that the product "Estimates Weeks Since Ovulation," is unambiguously true. Yet the district court erroneously found that packaging misleading based on a deeply problematic consumer survey, whose only objective questions showed that consumers were not actually misled. The Weeks Estimator's launch packaging, meanwhile, was neither literally false (because it *nowhere* said that it estimates pregnancy duration in the same way as a doctor) nor otherwise misleading (unless, as the district court did, one improperly applies a presumption of confusion based on SPD's supposed intent, and then relies exclusively on the same flawed consumer survey). And even if either the revised or launch packaging had been subject to an error-free falsity analysis, the district court made no finding that any confusion over how the Weeks Estimator measures pregnancy duration actually drove purchasing or injured consumers—both required elements for Lanham Act liability.

Third, even if liability itself were not premised on numerous errors, the injunction must be vacated. The injunction orders a mandatory nationwide recall, enjoins advertising that confused no one, forces SPD to change the FDA-mandated name of its product, and requires that SPD publish self-flagellating "corrections" in the press and to customers. These sweeping commands bear no reasonable relationship to any harm, purported or otherwise, in this case.

ARGUMENT

I. C&D'S LANHAM ACT CLAIM IS PRECLUDED

C&D's Lanham Act claim attacks the labeling and promotion of the Weeks Estimator as false and misleading. But the critical elements of SPD's marketing—from the detailed "indications for use" statement drafted by the FDA to the Weeks Estimator's very name—were reviewed, edited, and in many cases dictated by the FDA as part of an intensive Section 513 approval process that specifically considered the concerns at the heart of C&D's claim. Those critical elements, which reflect the FDA's considered judgment, *cannot be changed* without FDA approval. The district court nonetheless held SPD liable under the Lanham Act and entered a sweeping injunction that cannot be followed without violating the FDA's orders—reinforcing the fundamental conflict between C&D's Lanham Act claim and the FDA's exercise of its regulatory authority under the Food Drug and Cosmetic Act ("FDCA"). In the unique circumstances of this case, C&D's Lanham Act claim is precluded and the district court's injunction should be reversed or, at a minimum, vacated.

A. C&D's Lanham Act Claim Is Precluded By The FDA's Intensive Regulation Of SPD's Product

The conflict between C&D's Lanham Act claim and the FDA's exercise of authority over SPD is clear: the requirements imposed by the FDA prevent SPD from taking critical steps to avoid liability under C&D's Lanham Act theory.

Accordingly, C&D's theory of Lanham Act liability is precluded under controlling Supreme Court precedent that the district court never considered.[6]

1. C&D's Lanham Act claim is precluded under *PLIVA*

The question of whether two federal statutes conflict in a manner that precludes liability under one of them is analogous to the question of whether a federal law preempts a state law. The Supreme Court has thus noted that, in analyzing preclusion under the FDCA, preemption "principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). If anything, however, a preclusion claim is easier to establish than preemption, because it does not involve the same federalism concerns inherent in displacing a state law and there is no "presumption against preclusion." *Id.*

Here, the Supreme Court's preemption decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), is on point and requires preclusion of C&D's Lanham Act claim. *PLIVA* involved state law claims by plaintiffs who had suffered injuries allegedly due to a generic drug manufacturer's failure to provide adequate warning labels. *See* 131 S. Ct. at 2573. Under the governing interpretation of FDA rules, the warning labels on generic drugs were required to be the same as those on the

[6] This Court reviews such legal issues *de novo*. *E.g.*, *Goodspeed Airport LLC v. East Haddam Inland Wetlands & Watercourses Comm'n*, 634 F.3d 206, 209 n.3 (2d Cir. 2011).

brand-name drug, and the generic drug maker could not change or otherwise re-cast the label unless the brand-name maker did. *Id.* at 2574-76. The only way for the generic drug maker to change its label was to request permission from the FDA, which had discretion to grant or deny such permission. *Id.* at 2576-77.

The Supreme Court held that the state law tort claim in *PLIVA* was preempted because the defendant could not *unilaterally* change the label, and therefore could not comply with FDA requirements while avoiding state law liability. 131 S. Ct. at 2577-78. The Court rejected as irrelevant the suggestion that the generic drug maker could have sought discretionary FDA approval of a new warning label. *Id.* at 2577-78. The critical question was whether the defendant could have "independently" complied with FDA requirements while avoiding state tort law liability. *Id.* at 2579. The Court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2581.

The same framework governs the preclusion analysis here. *See American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) ("If FDA approval of the precise label used by a drug manufacturer is a defense to a consumer's product liability action, it should be, *a fortiori*, a defense

to a competitor's action under the Lanham Act."). Under *PLIVA*, the question is whether SPD "could independently do under [the FDCA] what [the Lanham Act purportedly] requires of it." 131 S. Ct. at 2579. Here, C&D's Lanham Act claim is precluded because SPD was not permitted to modify critical elements of the Weeks Estimator's labeling or messaging without discretionary FDA consent.

As discussed, the Weeks Estimator was subject to a rare and stringent form of FDA review under Section 513. *See* 21 U.S.C. § 360c(i)(1)(E). Under that provision, the FDA exercises statutory authority to "*require* a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling." *Id.* at § 360c(i)(1)(E)(i) (emphasis added). This process goes far beyond the general requirements and approval process imposed on a Class II medical device and allows the FDA to impose specific requirements on the labeling of the device. JA1992-1993; *accord* 21 U.S.C. § 360c(i)(1)(E)(ii)(II)-(III) (in Section 513 process, FDA "specif[ies] the limitations … not included in the proposed labeling" and may approve the device only once it "conforms to the limitations specified").

The FDA invoked Section 513 here to address the same issue at the core of C&D's Lanham Act claim—the risk that women using the Weeks Estimator might "misinterpret the weeks results to be a substitution for gestational age determination" as commonly calculated by doctors. JA7581. As part of its

intensive Section 513 review, the FDA exercised control over the Weeks Estimator's packaging in ways both large and small, requiring numerous changes. *See* JA7982 (citing Section 513 as basis for required limitations); JA3368 (same); *see also* JA2002 ("FDA makes final determinations of labeling requirements for [Section 513 approvals]").

For example, the FDA exercised control over the name of SPD's product. SPD originally proposed calling the product "Clearblue Advanced Pregnancy Test with *Conception Indicator*"—a name that it used outside of the United States and that would have substantially reduced any alleged confusion about the product's function. JA9004.21 (emphasis added); JA9680 (same); *see also* SPA99-100; JA9004.27; JA1759. But the FDA rejected SPD's original proposal, JA9004.161; JA9680, and subsequently told it to refer to the estimation feature as the "Weeks Estimation Indicator." JA7583 ("Please refer to the weeks indicator feature as the 'weeks estimation indicator' throughout all of your labeling (box labeling and package insert). The new name for your device should be modified to reflect this (e.g., Clearblue Advanced Pregnancy Test with Weeks Estimation Indicator)."); SPA99-100 ("The Hold Letter also requests changing the name of the product to the 'Weeks Estimation Indicator' rather than 'Conception Indicator,' which was SPD's initial name for the product."). The FDA later approved simplifying the

description to "Weeks Estimator," JA2030, a term that SPD cannot change without FDA permission, JA3370.[7]

The FDA also drafted and required a specific "indications for use" statement that addressed various concerns about potential uses of the Weeks Estimator. Among other things, it states:

> The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. …Your doctor may determine how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

JA3370; JA7582. The FDA reviewed the font size and placement of this statement on the side of SPD's box. *See, e.g.*, JA2056-2057. The FDA also addressed the issue of communicating these points in space-limited contexts, JA9004.6; JA1584, and later approved a specific short-form version, JA2178-2179.

The FDA additionally exercised control over a conversion chart comparing the estimate provided by SPD's product with what a doctor might tell a patient

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[7] SPD did briefly make changes to its web site—but not its labeling—when ordered to do so by the district court's injunction during a period when its product was off the market. The decision to make these changes under the threat of contempt sanctions in no way implies that SPD was free to make these changes earlier. Rather, the Hobson's choice forced upon SPD by the district court's injunction reinforces the stark conflict between the competing mandates of the FDCA and the injunction. *See infra* Part I.

using the LMP convention. SPD proposed including the chart on the *outside* of its box, JA9004.27; JA1595-1596; JA2317, as it had done elsewhere in the world, JA9650; JA9662. But the FDA's clearance letter approved the use of the conversion chart only on the package insert *inside* the box. JA3368-3369; *see also* JA1597; JA1599.

The FDA also reviewed the Weeks Estimator's packaging for style and form, including issues like font size and color. *See* JA2050 (in response to queries regarding the legibility of the text and labeling: "The font colors and backgrounds have been modified in the attached labeling so that the text is easier to read on both the box and package insert."); *see also, e.g.*, JA2031-2032.

The FDA revisited SPD's messaging again in 2013, after C&D filed complaints with the FDA that mirrored the claims it subsequently made in this lawsuit. At that time, the FDA not only mandated further changes to the Weeks Estimator's labeling, but also required changes to the content of SPD's television and internet ads. JA2180-2184; JA2194. For example, it required SPD to stop airing a national television commercial and approved a similar version of the commercial on condition that the full "indications for use" be displayed. JA2183-2184; JA2208-2217 (discussing digital ad).

As the district court admitted, "[t]here is no doubt the FDA subjected the Weeks Estimator's labeling to an extensive pre-approval process." *See* SPA101;

see also SPA99-100. The district court nonetheless concluded that multiple elements of SPD's FDA-controlled labeling and messaging either contributed to or failed to mitigate the allegedly false or misleading message on which it based its Lanham Act ruling. SPA30 (relying on product's name to find falsity); SPA31-32 (dismissing clarifications in FDA-drafted "indications for use" on side of package because the FDA-drafted statement was lengthy and FDA-approved font was deemed too small); SPA32 (disregarding information the FDA required to appear only on package insert inside the product's box).

In faulting SPD, the district court ignored the critical fact that SPD was not free to change the core elements of its FDA-mandated labeling and messaging. In the initial stages of the Section 513 review, for example, SPD asked whether, if "at a future point we wish to make changes to the device or to its labeling do the same criteria for deciding when to submit a 510(k) apply?" The FDA responded: "No, the same criteria will not apply. Following a [Section 513] decision, sponsors *must submit a new 510(k) in order to make changes to the limitation labeling (and related material).*" JA2002 (emphasis added). The FDA confirmed this point when it approved the Weeks Estimator, explaining in its formal Clearance Letter that "the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling." JA3370.

The FDA returned to this same theme in its 2013 review. In part because Section 513 review is so rare, SPD had believed that it could make certain minor changes to its labeling and marketing materials. *See supra* p. 10. But the FDA reprimanded SPD and emphasized that the limitations it imposes are "requirements and not suggestions." JA2171. Thereafter, even relatively minor decisions led to substantial exchanges with the FDA to secure the FDA's blessing that any changes were "acceptable to market." *See* JA1387 ("If any of the information you have provided changes (e.g. proposed labeling or proposed marketing strategy changes) please contact us *prior to marketing*." (emphasis added)).

The FDA's repeated emphasis that the changes it directed or approved were mandatory flowed directly from its statutory authority to "require" changes as part of Section 513 review. 21 U.S.C. § 360c(i)(1)(E)(i). The FDA's guidance on Section 513 likewise makes clear that further FDA review is required before *any* changes may be made for a device that has undergone Section 513 review. JA1995 ("The labeling limitations including in the [Clearance Letter] … are required by Section 513(i)(1)(E) of the Act. Therefore, a manufacturer must submit a new 510(k) before these limitations are modified *in any way or removed* from the device's labeling." (emphasis added)).

The extensive restrictions placed on SPD with respect to modifying the Week's Estimator's labeling and promotion are comparable to those in *PLIVA*.

Here, as in *PLIVA*, SPD is required to incorporate critical elements in its product packaging and messages that cannot be changed without prior FDA approval. Here, as in *PLIVA*, the theory of liability conflicts with those FDA requirements. And here, as in *PLIVA*, SPD cannot be held liable in light of this conflict.

2. *POM Wonderful* and *Wyeth* do not save C&D's Lanham Act claim

Without addressing *PLIVA*, the district court relied heavily on *POM Wonderful v. Coca-Cola*, 134 S. Ct. 2228 (2014), to support its rejection of preclusion. SPA102-107. But *POM* neither controls nor purports to control here. *POM* dealt with a Lanham Act claim involving juice labels that were not subject to any form of FDA preapproval. 134 S. Ct. at 2239 ("the FDA does not preapprove food and beverage labels under its regulations and …. does not necessarily pursue enforcement measures regarding all objectionable labels"). Coca-Cola was free to change its label at any time without FDA approval. And the relevant juice labeling regulations of general applicability provided only a floor, rather than a ceiling.

In that context, where it was easy to comply with both FDA labeling regulations and the Lanham Act, the Court held that a Lanham Act claim was not precluded, noting that "neither the statutory structure nor the empirical evidence of which the Court is aware indicates there will be any difficulty in fully enforcing each statute according to its terms." 134 S. Ct. at 2240.

The *POM* Court expressly contrasted that case with a scenario in which compliance with FDA rules would have presented an obstacle to complying with the duties imposed by a particular theory of liability under the Lanham Act. *See* 134 S. Ct. at 2240 (the "greater specificity" of FDA's statutory mandate to regulate food labels "would matter only if the Lanham Act and the FDCA cannot be implemented in full at the same time."). In particular, *POM* made clear that its reasoning did not necessarily extend to more stringent pre-approval type regimes, such as those in the medical arena. The Court said: "[T]he FDA does not preapprove juice labels under these regulations. That contrasts with the FDA's regulation of other types of labels, such as drug labels, see 21 U.S.C. § 355(d), and is consistent with the less extensive role the FDA plays in the regulation of food than in the regulation of drugs." 134 S. Ct. at 2235.

The regime at issue here—the Section 513 review process for medical devices, with its extensive oversight and comprehensive labeling mandates—is the exact type of stringent FDA regulation that the *POM* Court excluded from consideration. *See JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992 (C.D. Cal. 2014) ("This passage [in *POM Wonderful*] suggests, that at a minimum, the Court might find a Lanham Act claim precluded" if a "label were preapproved by the FDA.").

Ignoring the difference in the regulatory regimes at issue, the district court explained that "be it food or medical devices, '[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.'" SPA105 (quoting *POM*, 134 S. Ct. at 2239). But there are no "synergies" where the mandates imposed by "multiple methods of regulation" conflict, as they do here. *POM* cannot and does not control.

The district court's reliance on *Wyeth v. Levine*, 555 U.S. 555 (2009), was equally misplaced. In *Wyeth*, a preemption case involving an FDA-approved drug, the Court held that a drug maker could be held liable under state tort law for omitting a certain warning from its label. Crucial to the decision was the fact that the drug maker could *unilaterally* add the warning required by state tort law duties without waiting for FDA approval. *Id.* at 572-73. Thus *Wyeth*, like *POM*, dealt with the inapposite scenario in which no regulatory order or mandate prevented independent action to comply with a separate legal regime. Indeed, *PLIVA*, which came after *Wyeth*, expressly recognized this distinction. *See PLIVA*, 131 S. Ct. at 2581 ("The Court [in *Wyeth*] held that the lawsuit was not pre-empted *because it was possible for Wyeth … to comply with both state and federal law*." (emphasis added)).

PLIVA deals with the scenario at issue here, where unilateral compliance with multiple regimes is impossible. *POM* and *Wyeth* do not. Under *PLIVA*, C&D's claims are precluded.

3. C&D's Lanham Act claim is precluded under *Geier*

Preclusion is also proper here for a separate reason: It is necessary to preserve the FDA's considered policy judgment regarding the balance to be struck between competing messages. The FDA's comprehensive regulation of the Weeks Estimator reflects the FDA's expert judgment, after extensive review, about the most effective way to clarify the distinction between weeks since ovulation and the LMP convention for expressing pregnancy length. It also reflected the FDA's judgment regarding the appropriate communication of other issues. For example, the lengthy "indications for use" statement that the FDA drafted and required clarified not only that the "test provides a different estimate that cannot be substituted for a doctor's determination of gestational age," but also that it "is not intended for multiple pregnancies" and "cannot be used … to monitor the progression of pregnancy." JA3370.

C&D's Lanham Act claim seeks to elevate one of those messages over the others in a way that upsets the balance the FDA chose to strike. In these circumstances, preclusion is the only way to respect the FDA's judgment about how best to describe the function of the Weeks Estimator without detracting from

other important messages. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 881-882 (2000) (conflict preemption where tort liability was based on automaker's following airbag rules that "embodie[d] the [government's] policy judgment"); *cf. Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (holding that it was not "appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations").

B. At A Minimum, The District Court's Sweeping Lanham Act Injunction Is Precluded

Even if C&D's underlying Lanham Act *claim* were not precluded in its entirety, the district court's *injunction* should still be vacated. As an initial matter, a holding of partial preclusion would change the equitable balance and require reassessment of the injunction. More importantly, regardless of what happens with C&D's underlying Lanham Act claim, the injunction itself is precluded because SPD cannot comply with its terms "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." *PLIVA*, 131 S. Ct. at 2581.

Perhaps nowhere is this conflict more evident than with respect to the name of SPD's product. The district court expressly enjoined SPD from "us[ing] the words 'Weeks Estimator' in the Product's name unless it is modified within the name itself to make clear that it estimates weeks since ovulation only." SPA57.

The district court thus prohibited SPD from selling its product unless it changes the product's name, something SPD cannot do without FDA approval. The court's injunction therefore conflicts with the obligations imposed under Section 513 of the FDCA.

Similarly, the district court's injunction requires that "any packaging, advertising or promotional materials for the Product" that "promote the 'weeks estimating' feature of the Product"—which presumably includes any such materials that use the product's FDA-mandated name—contain a new, court-drafted statement in a font size and location dictated by the court. SPA56. Again, SPD cannot independently comply with this provision under the terms of its FDA approval.

The court-mandated statement also selectively addresses only the distinction between weeks since ovulation and weeks pregnant based on LMP, without including any of the *other* language that the FDA viewed as critical in crafting the "indications for use" statement—for example, the warning that the product should not be used to monitor the progression of pregnancy. JA3370. This decision to make one element more prominent risks upsetting the balance struck by the FDA and could cause customers to fail to read the "indications for use" as the integrated statement that the FDA intended. *See supra* pp. 31-32.

The district court even went so far as to prohibit the faithful depiction of the product display results because it considered such a display misleading. SPA56-57. This is, in substance, a conclusion that the *product*, not just the advertising, is inherently deceptive.

SPD continues to work diligently to seek FDA approval of a revised label and other materials that would satisfy the district court's injunction and ensure this unique product remains available to women. As of the filing of this brief, the FDA has not approved the changes, and it is impossible to prejudge the outcome. But even if the FDA does ultimately approve some or all of the changes mandated by the district court, it would not cure the error in the district court's injunction, which is premised on, and hopelessly entangled with, the erroneous notion that the district court could require extensive messaging regarding the Weeks Estimator that was different than the FDA's and impose liability on SPD for not doing so itself sooner.

Indeed, there is a notable disconnect between the district court's reasoning in rejecting SPD's preclusion claim and the scope of the district court's injunction. In its preclusion opinion, the district court said that "a finding that a medical device is falsely advertised will not itself *prohibit the use of a medical device* that the FDA has approved or *mandate any particular replacement labeling* different from what the FDA has already approved." SPA111 (emphasis added). Yet, in addition to ordering a nationwide recall of SPD's product, the district court did "mandate …

particular replacement labeling" that SPD cannot use consistent with the terms of its clearance. Even if this Court does not find that Lanham Act liability is precluded, this conflict between the district court's injunction and the FDA's requirements mandates that the injunction be vacated. *Cf. Silverstein v. Penguin Putnam, Inc.*, 368 F.3d 77, 83 (2d Cir. 2004) (vacating Copyright Act injunction as abuse of discretion without making liability determination).

II. THE DISTRICT COURT'S LANHAM ACT RULING WAS BASED ON A LEGALLY FLAWED ANALYSIS

To prevail on a false advertising claim under the Lanham Act, a plaintiff must establish that the challenged advertising message is (1) false, (2) material, (3) placed in interstate commerce, and (4) the cause or likely cause of plaintiff's injuries. *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255 (2d Cir. 2014). With the exception of the interstate commerce element, the district court's decision falls short at every step.

A. The District Court Erred In Basing Liability On The Revised Package

To show that an advertising message is false, a plaintiff must prove that the message is (1) literally false, or (2) impliedly false and "likely to mislead or confuse consumers." *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992) ("*J&J-Merck*"). The district court did not find that the Revised Packaging was literally false or

intentionally deceptive. SPA36. Rather, the court held only that the Revised Packaging was misleading, based on survey evidence purporting to show consumer confusion. SPA36-37. This was reversible error for two reasons.[8]

First, where an advertising claim is clear and objectively verifiable, as it is here, a court cannot resort to consumer survey evidence to determine that the claim is misleading. *See Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 250 (3d Cir. 2011); *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 885 (7th Cir. 2000). Here, the Revised Package prominently stated on the front that SPD's product is the "Only Test That Estimates Weeks Since Ovulation*":

JA3380. The asterisk further clarified this message by directing consumers to the FDA-approved "indications for use" on the side of the box, which has *always* stated in relevant part:

[8] A district court's determination that an advertisement is misleading is reviewed for clear error. *J&J-Merck*, 960 F.2d at 298.

> Your doctor may determine how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

JA3370. The Revised Package's clear message that the product measures weeks since ovulation is precisely the sort of "factually accurate and facially unambiguous statement [that] is not open to attack through a consumer survey." *Pernod Ricard*, 653 F.3d at 252.

The Seventh Circuit aptly illustrated the point in *Mead*. In that case, Similac, an infant formula, claimed to be the "1st Choice of Doctors." The district court found the claim false, relying on survey evidence that showed consumers understood the claim to mean that a majority of doctors preferred Similac. The Seventh Circuit reversed, holding that survey evidence cannot be used "to determine the meaning of words, or to set the standard to which objectively verifiable claims must be held." 201 F.3d at 886. The word "first," the court explained, "denotes rank in a series," not a fixed percentage, and, given the evidence in the record showing that more physicians preferred Similac than any other brand of infant formula, "it is all but impossible to call the claim of 'first choice' misleading." *Id.* at 884. The court concluded that "interpreting 'misleading' to include factual propositions that are susceptible to

misunderstanding would make consumers as a whole worse off by suppressing truthful statements that will help many of them find superior products." *Id.* at 886.

Mead is directly on point. The district court here erred by going directly to consumer survey evidence to determine that the clear, objectively verifiable message that the product "Estimates Weeks Since Ovulation" actually meant something different: that the product provides an estimate of weeks pregnant that is consistent with a doctor's estimate. Here, too, consumers have been made "worse off by suppressing truthful statements that would help many of them find superior products." Indeed, the Weeks Estimator is the *only* pregnancy test with the ability to estimate weeks since ovulation, information that C&D's own study showed women consider valuable. JA2632. The unambiguous, verifiably true claim that the Weeks Estimator gives an estimate of "weeks since ovulation" cannot be rendered false or misleading by reference to a consumer survey, and any confusion that might arise is simply not within the purview of the false advertising law.

Second, even if the district court could properly consider the survey conducted by C&D's expert, Hal Poret, the survey was seriously flawed, rendering the results too unreliable to support a finding of consumer confusion. Poret's survey, described in ¶¶ 13-101 of his direct testimony, JA1546-1574, purported to measure whether and to what extent the Launch Package and the Revised Package

communicated to prospective purchasers of home pregnancy tests the following messages: (i) the Weeks Estimator estimates the number of weeks a woman has been pregnant (the "weeks pregnant" message), and (ii) the number of weeks the Weeks Estimator estimates is the same number of weeks pregnant that a doctor would tell her (the "same as a doctor" message). JA1543.

The court did not find the "weeks pregnant" message false. SPA27. (declining to determine when pregnancy begins). Rather, the court based its liability determination exclusively on the conclusion that the packages falsely conveyed a "same as a doctor" message. SPA30-31 (Launch Package); SPA37 (Revised Package). In particular, the district court relied on Poret's finding that "16.0% or 17.3% (depending on the base used) of [survey] participants" "understood the Revised Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate." SPA37. But this survey finding is unreliable due to (1) the survey's failure to test the critical issue in the case—whether respondents received the "same as a doctor" message as a result of the packages or due to their pre-existing beliefs—and (2) the survey's use of leading questions. *J&J-Merck*, 960 F.2d at 300 ("evidentiary value of a survey's results" depends upon "whether the questions are directed to the real issues, and whether the questions are leading or suggestive" (internal quotation marks omitted)).

The sole question in Poret's survey testing whether the packages conveyed the "same as a doctor" message was the final question:

> Question 220: Based on what the box communicated, do you think the product's estimate of weeks is telling you …
>
> 1. The **same** thing as when a doctor gives you an estimate of weeks
> 2. A **different** thing than when a doctor gives you an estimate of weeks
> 3. Or, do you not have an opinion.

JA1557; JA6680. The survey's preceding questions asked open-ended questions about what the package communicated in general and then more focused questions on what the package communicated about a weeks estimator. JA1556; JA6679-6680.

The first flaw with this approach is that the survey did not test the key issue in the case: whether the "same as a doctor" message was conveyed *by the Revised Package* or was a result of women's *pre-existing beliefs* as to how a doctor might measure pregnancy. JA1688 ("A woman might well believe—correctly or not—that doctors estimate weeks since ovulation. In that case, there is no reason to conclude she has been misled *by the Product packaging*."). Take, for example, a woman who, upon getting a "pregnant" result from a pregnancy test, calculates how "far along" she is based on when she believes she was ovulating and had intercourse. In making this estimate, this woman may (logically) believe that this is how a doctor would measure pregnancy. After all, it is biologically impossible

to be pregnant at the time of one's last LMP. JA1670, JA1675. Any confusion, then, would result from the woman's pre-existing belief of how a doctor would measure pregnancy and the medical community's rather counter-intuitive convention, rather than any false or misleading aspect of the product.

This is not a far-fetched hypothetical. Poret himself acknowledged that women may measure pregnancy this way. JA9446. Indeed, the percentage of women who gave a "same as a doctor" response to Question 220 *rose* from 18% on the Launch Package to 24% on the Revised Package, JA1575, which added a prominent statement that the product "Estimates Weeks Since Ovulation."

Because Poret's survey did not include a proper control asking women about their pre-existing beliefs regarding how a doctor would estimate pregnancy, the survey "shed[s] no light on the question that is key to [plaintiff's] false advertising claims," *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 279 (4th Cir. 2002), and cannot support a finding of consumer confusion. *Compare McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226, 244, 252-53 (S.D.N.Y. 2005) (survey controlled for pre-existing belief), *with Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp. 2d 594, 601 (D.N.J. 2003) (lack of a proper control makes it impossible to "separate the wheat (the effect of the advertisement, alone, on the participant) from the chaff (the effect of the participant's prior knowledge and/or prior (mis) conceptions)").

The results of Question 220 were also skewed by the close-ended and leading nature of the question. "It is well recognized that closed-end or multiple-choice questions are inherently suggestive and invite guessing by those who did not get any clear message at all." *American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 581 (S.D.N.Y. 1987). By presuming within the question itself that the package contained some comparison between the product's estimate of pregnancy and a doctor's, the question "caused respondents to focus on [a comparison] even if they did not recall anything about [such a comparison] from the advertising." *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 352 (S.D.N.Y. 2008); *see also Coors Brewing Co. v. Anheuser-Busch Companies, Inc.*, 802 F. Supp. 965, 972 (S.D.N.Y. 1992) (question asking whether "Coors Light and Natural Light are made the same way or different ways" "assumes that the commercial conveys some message comparing how the two beers are made" and caused percentage of consumers who indicated mistaken belief that the two beers are made in different ways to jump from between 3-9% to 36.18%); *American Home Prods.*, 654 F. Supp. at 582 (question presuming ad compared ibuprofen's and aspirin's propensity to cause gastric ulcers could mislead respondents into believing that the ad in fact represented that ibuprofen caused gastric ulcers).

The "no opinion" choice and instruction not to "guess" did not cure the problem because the list of answer choices was incomplete, the most obvious

omission being "the box does not communicate *anything* about a doctor's estimate of weeks." In a multiple-choice question like this, "'the response chosen will be meaningful only if the list of choices is exhaustive, that is, if the choices cover all possible answers a respondent might give to the question.'" *Procter & Gamble Pharm., Inc. v. Hoffmann-LaRoche Inc.*, 2006 WL 2588002, at *23 n.66 (S.D.N.Y. Sept. 6, 2006) (quoting Shari Seidman Diamond, *Reference Guide on Survey Research*, *in* Federal Judicial Center, *Reference Manual on Scientific Evidence* 253 (2d ed. 2000)).

Given these flaws with the close-ended question, the far more probative evidence of whether the packages communicated the "same as a doctor" message were the answers to the open-ended questions asking respondents what the package communicated in general. *See Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 1991 WL 206312, at *8 (S.D.N.Y. Oct. 1, 1991) (answers to open-ended question "most accurately measure consumer understanding"), *aff'd*, 960 F.2d 294 (2d Cir. 1992). Tellingly, fewer than 10 women out of the 400 total who viewed a non-control-group package (i.e., 2% or less) reported a "same as a doctor" message in response to the open-ended questions. *See* JA6704-6764. This is far below the threshold required to establish "substantial" confusion. *See Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm.*, 19 F.3d 125, 134 (3d Cir. 1994) (survey showing

that "only 7.5% of the responses" recounted the allegedly misleading message "in response to open-ended questions" "is an insufficient number to show that, under the Lanham Act, the advertising tends to deceive or mislead 'a substantial portion of the intended audience'"); *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995) (evidence that less than 3% of potential buyers interpreted the advertising in the allegedly misleading way did "not constitute proof that a significant portion of recipients were deceived").

The flaws in Poret's survey are critical because even the results relied upon by the district court indicate that *over 82% of women* viewing the Revised Package did *not* receive a "weeks pregnant" and "same as a doctor" message, meaning that the *vast majority of women were not confused*. SPA36-37; JA1576. Indeed, even putting the survey's flaws aside, C&D's claim that a "substantial percentage" of consumers were misled—as required to support an implied falsity finding—falls of its own weight.

B. The District Court Erred In Basing Liability On The Launch Materials

The district court found that the Launch Package, TV Commercial, and other Launch Advertising (collectively, "Launch Materials") were literally false. In the alternative, the court found the Launch Materials impliedly false and applied a presumption of consumer confusion based on its finding that SPD acted deliberately to deceive consumers. Finally, as to the Launch Package only, the

court held that it was impliedly false based on evidence of actual confusion and evidence of likelihood of confusion in the form of the Poret survey. All of these findings were in error.

1. The district court's literal falsity analysis was flawed

The district court acknowledged that "the Launch Package does not make an express statement that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant." SPA30. The district court nonetheless found the Launch Package and other Launch Materials "false by necessary implication" based on the premise that information about "weeks" in conjunction with references to pregnancy necessarily communicates the message that the product provides "an estimate of weeks pregnant that is consistent with a doctor's estimate." SPA30. This leap of logic was clear error.[9]

To be literally false, an advertising message must be *unambiguous*. "[I]f the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false" or "false by necessary implication." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).

Whether an advertising message is unambiguous depends on how the "reasonable ordinary consumer" would understand it, regardless of whether it has a

[9] Literal falsity is a finding of fact reviewed for clear error. *Johnson & Johnson v. GAC Int'l, Inc.*, 862 F.2d 975, 979 (2d Cir. 1988).

specialized meaning to a particular industry. *North Am. Olive Oil Ass'n v. Kangadis Food Inc.*, 962 F. Supp. 2d 514, 520 (S.D.N.Y. 2013); *see also Johnson & Johnson v. GAC Int'l, Inc*., 862 F.2d 975, 980 (2d Cir. 1988) (evaluating literal meaning of advertising claim by reference to how the likely purchasers, orthodontists, would understand the claim); *Highmark, Inc. v. UPMC Health Plan, Inc*., 276 F.3d 160, 172 (3d Cir. 2001) (adoption of term's "plain meaning" over technical one was appropriate "as the Ad was addressed to the public and not the industry").

For example, in *North American Olive Oil Association*, the court found that the label of a refined olive oil claiming to be "100% Pure Olive Oil" was not literally false even though that claim did not conform to industry labeling standards (which made a distinction between "pure" and refined olive oil). The court reasoned that the "reasonable ordinary consumer" would interpret "100% Olive Oil to refer simply to a product that contains olive oil … and nothing but olive oil," which would be true. 962 F. Supp. 2d at 520. That this consumer might also believe or assume that the olive oil's "100% Pure" claim conformed to industry labeling standards (because of a pre-existing belief that all retail food products adhere to industry labeling requirements) would not render the claim "false by necessary implication."

Here, too, the "reasonable ordinary" woman in the market for a home pregnancy test may accurately understand the product's "weeks" claim as weeks since ovulation/fertilization without forming any belief about whether that measure is the same or different as the LMP convention used by doctors. And even if she believes the measure is the same, that view may come from a pre-existing belief that a doctor also measures pregnancy from ovulation/conception, not because the message is necessarily implied by the Launch Materials. *See supra* pp. 40-41. The "same as a doctor" message is simply not "recognize[d] … as readily as if it had been explicitly stated," as required to be literally false by necessary implication. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 587 (3d Cir. 2002) (internal quotation marks omitted); *see also United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1181 (8th Cir. 1998) ("The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, … the less likely it is that a finding of literal falsity will be supported.").

Indeed, C&D's own survey fatally undermines the district court's "false by necessary implication" finding. According to the Poret survey, only 18% or 21.8% of women viewing the Launch Package received a "weeks pregnant" and "same as a doctor" message. JA1566. Even were those figures accurate rather than overstated, *see supra* pp. 39-44, it is impossible to reconcile the court's conclusion

that the Launch Materials *unambiguously* conveyed an allegedly false message with survey results showing that four-fifths of women who viewed the Launch Package did not receive the challenged message.

The analysis is no different for the TV Commercial that ran during the launch period. The commercial features an exchange in which one woman announces she is pregnant and tells her friend "Two weeks," prompting the question "You already went to the doctor?" and the response "Not yet, but I took this new Clearblue test." JA3384. The ability to get test results before seeing a doctor is not an "unambiguous" statement that those results will be expressed using the same convention a doctor would use. In addition, for two of the fifteen seconds of the commercial, the words "ESTIMATED WEEKS SINCE OVULATION" appear on screen, and for nine of the fifteen seconds, a statement at the bottom of the screen says:

> Word 'weeks' on display is for illustration only. For home use only. Always consult a doctor if you suspect you are pregnant and to confirm, *date* and monitor pregnancy. Not for multiple pregnancies. Estimates weeks *since ovulation* up to 3+ weeks. Do not use to monitor pregnancy progress or duration.

JA3384; SPA14 (emphases added). As with the Launch Package, it was clear error to say that "the commercial's advertising message is unambiguous and is literally false." SPA37.

2. The district court erred in applying an intent-based presumption of consumer confusion

The district court's alternative holding that the Launch Materials were misleading relied heavily on a *presumption* of consumer confusion arising from the conclusion that SPD "intentionally set out to deceive consumers" through conduct of an "egregious nature." SPA33 (applying presumption to Launch Package). Indeed, this presumption was the *only* support for the district court's conclusion that the TV Commercial and other launch-period advertising caused consumer confusion. SPA39-40. The district court's application of this intent-based presumption, however, was fundamentally flawed.

First, the district court's finding of intentional deception was, like the court's literal falsity analysis, improperly premised on the notion that any message about "weeks" or "weeks pregnant" necessarily conveyed a "same as a doctor" message.[10]

Second, the district court made no attempt to justify a finding of intent to deceive in connection with the Launch Package itself. The premise of the FDA's Section 513 approval had been that any confusion could "be prevented given adequate device labeling." JA7582. Among other things, the FDA mandated a

[10] Though SPD contests the district court's credibility findings, many of these findings are simply beside the point, as they focused on intent to convey the "weeks pregnant" message, not the "same as a doctor" message that the court found false.

detailed "indications for use" statement making clear that the "test provides a different estimate that can not be substituted for a doctor's determination of gestational age." JA7582. There is no evidence that SPD thought this statement was ineffective or thought any additional changes to the Launch Package would deceive consumers.

Third, the district court ignored the product's proven success outside the United States, where it had been marketed as the "Conception Indicator" and included a chart on the outside of the package comparing the product's estimate of pregnancy to a doctor's. JA1759, JA9662. The product's success with this labeling abroad undermines the court's assumption that SPD had a financial motive to try to obfuscate how the product functioned. JA1761-1762.

Fourth, the internal emails that the district court cited show at most that SPD recognized the need to balance the risk of consumer confusion against the understandable desire to market the truthful fact that the product can measure "weeks," even before a customer visits a doctor. For example, Ryan Daly's email about the TV Commercial viewed as "low" the risk the FDA might notice the commercial on its own. JA8543. It also expressed concern about confusing the television networks with excessive detail beyond the condensed indications for use statement that appeared at the bottom of the screen in the commercial. JA8543. But both of these statements were made in the context of an email that said "I think

the copy does a great job of *not pushing this as a replacement to Dr*." JA8543 (emphasis added). Thus, rather than evincing an intent to deceive consumers that the product measures pregnancy the same way a doctor does, the email shows that SPD, having come to its own judgment that the disclosures in the commercial were sufficient, simply wished to avoid the risk that the network might be confused by additional detail. JA8543, JA9576-9577.

Another email that the district court found "troubling," SPA24, showed only that Kristen Suarez thought consumers would piece together a "weeks pregnant" message from the proximity of the words "[p]regnant" and "weeks," JA8554. Again, this was not evidence of intent to deceive but an effort to reconcile FDA constraints that were sometimes in tension. For example, SPD believed the FDA wanted to avoid the phrase "weeks pregnant," but the FDA had expressly approved use of the phrase "weeks along." JA9662. Suarez was seeking to thread that needle. In any event, the district court did not rest its decision on the alleged falsity of a "weeks pregnant" message, and nothing in the email suggested that Suarez intended to convey the "same as a doctor" message on which the court's decision was actually based.

Evidence of the relevant intent to deceive here is thin at best, and certainly not present in the "egregious proportions that would warrant a presumption."

Rorer, 19 F.3d at 132. Thus, the district court clearly erred when it applied an intent-based presumption of consumer confusion to the Launch Materials.

3. The district court erred in admitting, and relying upon, the Poret survey

Finally, the district court held that the Launch Package (but not the other Launch Materials) was impliedly false based on the Poret survey. For the reasons discussed above, the Poret survey does not reliably measure consumer confusion and cannot support an implied falsity claim. *Supra* pp. 39-44. As for actual evidence of confusion, C&D is left with a single news report of one woman who became concerned her "baby was not developing correctly," SPA33, and seventeen total complaints made in the United States to SPD's consumer care line allegedly indicating that the consumer mistakenly believed the product estimates pregnancy the same way a doctor would, SPA34. Seventeen complaints on the relevant issue, compared to the 1,866,215 Weeks Estimators sold from August 2013–June 2014, is not just "modest," as the district court found, SPA34, but astoundingly low for purportedly misleading advertising. Such scant evidence of actual confusion cannot support, and indeed rebuts, a finding of implied falsity. JA1667.

C. The District Court Erred In Finding Materiality And Likelihood Of Injury

To prevail on its Lanham Act claim, a plaintiff must show not only falsity but also that the false message is material, meaning that it is "likely to influence

purchasing decisions.'" *NBA v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997) (quoting *AT&T Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1428 n. 9 (3d Cir. 1994)); *see also* 5 *McCarthy on Trademarks* § 27:35 (4th ed.). ("Plaintiff must make some showing that the defendant's misrepresentation was 'material' in the sense that it would have some effect on consumers' purchasing decisions."). The plaintiff must also demonstrate that the false message is likely to cause damage to the plaintiff. *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980). The district court's analysis of materiality and likelihood of injury here was fundamentally flawed.

1. The district court erred in finding materiality

The district court based its materiality determination on the conclusion that the Weeks Estimator's "ability to estimate weeks" was "an inherent quality or characteristic of the product as it is the key feature that differentiates it from the many other home pregnancy tests on the market." SPA40. This was error because the proper inquiry is whether the purportedly *false message* is what influenced purchasing decisions. The weeks estimator function may have been attractive to consumers. But the "ability to measure weeks" is not the false message found by the district court. Rather, the court was required to find that the "same as a doctor" message drove purchases—i.e., had women known the Weeks Estimator's method of measuring pregnancy was different from a doctor's method, women would not

have purchased the Weeks Estimator. *See, e.g.*, *NBA*, 105 F.3d at 855 (false claim that sports score-tracking device provided "updated game information direct from each arena" when it actually relied on reporters listening to TV and radio broadcasts was not material to consumers' purchasing decisions). The district court made no such finding.[11]

2. The district court erred in finding likelihood of injury

Similarly, in demonstrating likelihood of injury, a plaintiff must show a logical causal connection between the false message and its sales position. *Carter-Wallace, Inc.*, 631 F.2d at 190. The district court found that C&D established this logical causal connection based on evidence that SPD's market share increased and C&D's market share decreased upon the launch of the Weeks Estimator. SPA42. But changes in market share following the launch of the Weeks Estimator do not show that the false message—*i.e.*, the "same as a doctor" message—is what caused C&D's loss in market share. C&D may have lost the same market share even absent the allegedly false message, for any number of reasons, not the least because consumers who perfectly understood SPD's product may have preferred to know the extra information that the product accurately provided. JA1761-1762

[11] Nor could it, as C&D's survey did not purport to address the materiality of the "same as a doctor" message. JA9447-9448 (Poret agreeing that "there was nothing that – that the survey was not specifically designed to get at [whether the allegedly false messages would drive consumer purchases]"); JA1577-1578 (giving opinion on materiality of weeks estimator feature, but not "same as a doctor" message).

(discussing product's success where marketed as the "Conception Indicator").[12] Because C&D has not "distinguish[ed] between the lost sales it believes it would experience from lawful competition and truthful advertising from the lost sales it believes it would experience from the alleged false advertising," *Procter & Gamble*, 574 F. Supp. 2d at 349, C&D has failed to show injury.

III. THE DISTRICT COURT'S INJUNCTION IS VASTLY DISPROPORTIONATE TO THE PURPORTED HARM TO BE REMEDIED

Though "[a] district court has a wide range of discretion in framing an injunction," "the essence of equity jurisdiction has been the power to grant relief no broader than necessary to cure the effects of the harm caused by the violation." *Forschner Group, Inc. v. Arrow Trading Co.*, 124 F.3d 402, 406 (2d Cir. 1997). Accordingly, "[i]njunctive relief should be narrowly tailored to fit specific legal violations" and "should not impose unnecessary burdens on lawful activity." *Patsy's Brand, Inc. v. I.O.B. Realty, Inc.*, 317 F.3d 209, 220 (2d Cir. 2003). This Court may reverse (or narrow) the district court's permanent injunction for abuse of discretion, which may be found where the injunction is overly broad or relied on clearly erroneous findings of fact or an error of law. *Starter Corp. v. Converse, Inc.*, 170 F.3d 286, 300 (2d Cir. 1999).

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[12] The Poret survey, according to which over 82% of women were not deceived, supports the conclusion that sales could well have been driven by women who were *not* confused by the product. SPA36-37; JA1576.

As an initial matter, the breadth of the injunction in this case is not supported by the court's own findings. The injunction prohibits all Revised Advertising described in pages 16-19 of its July 1 Opinion, "including the Internet-Only Commercial." SPA56. But the court made no findings of falsity as to any of the Revised Advertising except the Revised Package. Indeed, the court expressly noted that "C&D's post-trial briefing did not contain any specific arguments regarding the Internet-Only Commercial, nor did it offer any evidence during trial of consumer confusion regarding the Internet-Only commercial." SPA40 n.21.

An injunction that "exceeds the scope of the [factfinder's] findings" is "overly broad and, in that respect, represents an abuse of the discretion of the district court." *Starter Corp.*, 170 F.3d at 300. Thus, in *Starter Corp.*, this Court vacated an injunction against use of a mark on "all footwear when in combination with any other words or designs" because the jury's infringement findings went only to the marks used alone and were limited to "athletic footwear." 170 F.3d at 300 (internal quotation marks omitted); *see also Waldman Publ'g Corp. v. Landoll, Inc.*, 43 F.3d 775, 785 (2d Cir. 1994) (in false designation of origin case, limiting scope of injunction to just those acts violating the Lanham Act—falsely representing the source of books—rather than restraining defendant from publishing books altogether). At a minimum, the Revised Advertising must be excluded from the injunction's reach.

The inflammatory language of the court-mandated corrective notices is also improper. The notices, drafted by the court, state in part:

> Church & Dwight filed a civil suit against SPD Swiss Precision Diagnostics GmbH, manufacturer of Clearblue®, alleging false and misleading advertising. On July 1, 2015, the United States District Court for the Southern District of New York ruled in favor of Church & Dwight and has issued the enclosed permanent injunction with respect to the Clearblue® Advanced Pregnancy Test with Weeks Estimator, enjoining previous advertising for the Product.

SPA57-60. This notice is unnecessarily inflammatory, going beyond correcting consumer confusion and penalizing SPD by branding it as a false advertiser. The notice thus mandates commercial speech with a punitive, rather than remedial, purpose, contrary to goals of the Lanham Act. *See Merck Eprova AG v. Gnosis S.p.A.*, 2013 U.S. Dist. LEXIS 49798, *4-5 (S.D.N.Y. Mar. 7, 2013) ("Lanham Act awards must be remedial, not punitive, in nature….").

The sweeping scope of the corrective advertising campaign is also unwarranted. "An order of corrective advertising must be reasonable and causally related to the false advertising." *Merck Eprova*, 2013 WL 364213, at *7 (internal quotation marks omitted), *aff'd*, 760 F.3d 247 (2d Cir. 2014). Here, the court ordered SPD to undergo a massive campaign that included (i) sending corrective notices to all retailers, e-commerce websites, brokers, distributors, dealers, wholesalers, importers, and other non-consumer purchasers, (ii) publishing corrective notices in retail circulars, internet banners, and three magazines

circulated nationwide, and (iii) posting corrective notices, for a period of 1 year, at all trade shows, professional meetings, the Clearblue website, a standalone page on the Clearblue website dedicated solely to the corrective notice, the Clearblue YouTube channel, and the Clearblue Facebook page. All of this is in addition to other injunctive relief issued by the court, including requiring SPD to pull the product from shelves and refrain from marketing the product in its current (revised, FDA-approved) form.

The sweeping scope of the injunction contrasts with the fact that the materials that concerned the court the most, those that warranted the court's presumption of consumer confusion, were in the public domain for a relatively short time, more than 19 months ago. Since then, SPD has marketed the product with the Revised Advertising, which enhances the visibility of the message that the product measures weeks since ovulation and which, according to the court, over 82% of women accurately understand. *See* SPA36-37; JA1773-1777; JA3165-3166 (screenshot of webpage clearly displaying chart comparing product estimate of pregnancy to doctor's estimate). There has also been substantial turnover among the women in the market for home pregnancy tests. Moreover, the injunction orders SPD to do something it had already done as part of the product rollout: "produce a video … explaining the difference between the Product's estimate of weeks since ovulation and how a doctor dates pregnancy from last

menstrual period," SPA60; JA1765; JA3221 (Clearblue video of doctor explaining the difference between product's and doctor's estimates). The outsized corrective advertising campaign demanded here is hardly necessary to remedy the theoretical amount of consumer confusion, if any, that may still exist. *See Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.*, 1994 WL 16799629, at *9 (W.D. Mo. Sept. 30, 1994) (declining to award corrective advertising where "[m]uch of the advertising the Court finds violative of the Lanham Act … has been voluntarily withdrawn"), *aff'd in part, vacated in part on other grounds*, 93 F.3d 511 (8th Cir. 1996).

The breadth of the ordered corrective advertising is all the more extraordinary considering the thin evidence of actual consumer confusion in the record. Without the intent-based presumptions applied by the court and Poret's survey, the results of which should be discounted for reasons discussed above, C&D is left with the single news report of the woman concerned her "baby was not developing correctly," SPA33, and the 17 total complaints made in the United States to SPD's consumer care line (compared to 1,866,215 Weeks Estimators sold) complaining that the consumer mistakenly believed the product estimates pregnancy the same way a doctor would. SPA34. Because the purpose of corrective advertising is to remedy consumer confusion, the scope of the corrective advertising ordered should reflect the actual consumer confusion to be remedied.

Cf. Eu Yan Sang, Int'l Ltd. v. S & M Enterprises (U.S.A.) Enter. Corp., 2010 WL 3824129, at *6 (E.D.N.Y. Sept. 8, 2010) (denying corrective advertising monetary award absent "evidence of actual confusion by consumers"), *report and recommendation adopted*, 2010 WL 3806136 (E.D.N.Y. Sept. 23, 2010). Here, that requires drastically narrowing, or eliminating altogether, the corrective advertising campaign.

CONCLUSION

For the foregoing reasons, the district court's injunction and the Lanham Act ruling on which it is based should be reversed. In the alternative, this Court should vacate the injunction and remand.

Respectfully submitted.

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October 9, 2015

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 13,823 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Seth P. Waxman
SETH P. WAXMAN

October 9, 2015

SPECIAL APPENDIX

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co., Inc., Plaintiff, –v– SPD Swiss Precision Diagnostics, GmbH, Defendant.	14-CV-585 (AJN) OPINION & ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Church & Dwight Co, Inc. ("C&D") and Defendant SPD Swiss Precision Diagnostics, GmbH ("SPD") are leading manufacturers of home pregnancy tests, and they fiercely compete for market share in this product category. The present dispute between the parties concerns SPD's recently launched "Clearblue Advanced Pregnancy Test with Weeks Estimator" ("Weeks Estimator"), which the Food and Drug Administration ("FDA") cleared for the intended use of telling a woman (1) whether she is pregnant and, if she is pregnant, (2) how many weeks have passed since she ovulated. C&D contends that the product's name and advertising convey the false message that the product tells a woman how many weeks pregnant she is consistent with how a doctor would estimate weeks pregnant. This is false, C&D contends, because doctors estimate pregnancy duration based on how many weeks have passed since a woman's last menstrual period—not weeks since ovulation.

In April 2015, the Court presided over a two-week bench trial. Following this trial and with the benefit of post-trial briefing, the Court makes the following findings of fact and conclusions of law, which are expanded upon below: (1) SPD engaged in false advertising in violation of the Lanham Act; (2) SPD engaged in intentional deception of an egregious nature; (3) C&D is entitled to a permanent injunction; (4) SPD engaged in false advertising in violation

of New York State law; and (5) C&D failed to prove that SPD breached the parties' prior settlement agreement.

I. PROCEDURAL HISTORY

Shortly after this action commenced in early 2014, C&D moved for a preliminary injunction and SPD moved to dismiss C&D's complaint. SPD's primary argument in opposition to a preliminary injunction and in favor of dismissal was that the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, precludes C&D's Lanham Act claim. In an Opinion and Order Dated June 3, 2014, the Court denied SPD's motion to dismiss and consolidated the preliminary injunction with a bench trial on liability pursuant to Federal Rule of Civil Procedure 65(a)(2). *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 76752 (S.D.N.Y. June 3, 2014) ("*Church & Dwight I*"). At the parties' request, the Court also bifurcated liability and damages. Dkt. No. 42.

In advance of trial, SPD submitted two motions *in limine*. First, SPD moved to limit the scope of the case to the ten pieces of advertising attached to C&D's Complaint, generally referred to as the "launch" advertising for the Weeks Estimator. On October 28, 2014, the Court denied that motion, finding that a prior arbitration between the parties cleared the way for C&D's lawsuit and that C&D framed its Complaint in terms of false messages, not specific pieces of advertising. *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 158551 (S.D.N.Y. Oct. 28, 2014) ("*Church & Dwight II*").

Next, SPD renewed its previously rejected preclusion argument, contending that the Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), and additional documentary evidence provided support for this preclusion defense. The Court, however, held that *POM Wonderful*'s analysis bolstered its prior conclusion that the FDCA did not preclude the Lanham Act claim here. *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2015 U.S. Dist. LEXIS 67187, at *22-23 (S.D.N.Y. Mar 24, 2015) ("*Church & Dwight III*"). *POM Wonderful* observed that the FDCA and Lanham

Act complement each other in major respects and that the remedies of the two acts promote a "fundamental" harmony; among other things, "'[t]he FDA . . . does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess.'" *Id.* at *21 (quoting *POM Wonderful*, 134 S. Ct. at 2238-39). Drawing on this analysis, the Court concluded that "the FDA's perspective and expertise as compared to the knowledge of day-to-day competitors is at least as limited with respect to medical devices as it [was] for food and beverage labeling" in *POM Wonderful*. *Id.* at *23. In short, the Court held that it would "not 'elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act' because 'the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels.'" *Id.* at *29 (quoting *POM Wonderful*, 134 S. Ct. at 2241).

Also in advance of the bench trial, SPD submitted five motions and C&D submitted one motion to exclude expert witness testimony pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See* Dkt. Nos. 254, 265, 267, 269, 271, 273. The Court reserved decision on the *Daubert* motions prior to and during trial, but denied all of them following the close of trial. Tr. 1406:5-8. Bearing in mind that the *Daubert* gatekeeping standard is of less relevance, and thus applied more flexibly, when, as here, the judge is the factfinder, the Court concluded the testimony was admissible because it was based on sufficient facts or data, the product of reliable principles and methods, and reliably applied to the facts of this case. *See generally Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 579, 629, 645-46 (S.D.N.Y. 2007).

The Court conducted the eight-day bench trial in accordance with its Individual Practices in Civil Cases for non-jury proceedings. Prior to trial, the parties submitted declarations of direct and rebuttal testimony as well as copies of anticipated exhibits and deposition designations that they intended to use at trial. The parties also submitted proposed findings of fact and conclusions of law. At trial, the parties called only those witnesses whom they intended to cross-examine and played video depositions of witnesses who were unavailable. In all, the Court received direct testimony declarations from 17 witnesses, 15 of whom also provided live

testimony, as well as several hundred exhibits from both parties.[1] Following trial, the parties filed post-trial briefing and updated proposed findings of fact[2] that were fully submitted on May 20, 2015.

II. FINDINGS OF FACT[3]

Semantic disputes complicated much of this case. Stripped to the essential facts, which are described in greater detail below, the case is quite simple. Doctors have a number of ways to determine pregnancy duration, also known as gestational age, but they have a standard convention for expressing it. This standard convention expresses pregnancy duration in terms of the number of weeks that have passed since a woman's last menstrual period ("LMP"); that is, a woman's expected date of delivery is 40 weeks after her LMP, so if a woman is pregnant and 4 weeks have passed since her LMP she is said to be 4 weeks pregnant. SPD's Weeks Estimator tells a woman if she is pregnant and provides an estimate of the number of weeks that have passed since a woman last ovulated, which is, on average, two weeks after a woman's LMP. Thus, the Weeks Estimator provides an estimate of "weeks" that is expressed differently from the standard convention for expressing pregnancy duration. Despite this inconsistency, SPD's advertising for the Weeks Estimator conveys the message that the product provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. Therein lies the problem for SPD.

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[1] Direct and rebuttal testimony declarations are cited using the last name of the witness followed by DT or RT and refer to the final declarations as modified at trial. *See* Dkt. No. 363. The trial transcript is cited using Tr. followed by the page and line number for the citation. *See* Dkt. Nos. 373-388. C&D's admitted exhibits are cited as PTX; SPD's admitted exhibits are cited as DTX. *See* Dkt. No. 363. The Court addresses certain objections to exhibits herein; to the extent not expressly addressed at trial or in this Opinion, the Court hereby overrules the objection or concludes it was waived or abandoned. Due to the multiple briefs and other filings submitted over the course of this case, unless otherwise noted, the Court refers to the parties' filings using the Court's Electronic Case Filing ("ECF") docket numbers, abbreviated as Dkt. No. __.

[2] Both parties submitted post-trial proposed findings of fact and were provided an opportunity to respond to each other's proposed findings of fact with opposing record citations. *See* Dkt. Nos. 369, 370, 372, 392. The abbreviation "PPF" represents Dkt. No. 372, which incorporates C&D's proposed findings of fact and SPD's responses. The abbreviation "SPD PPF" represents Dkt. No. 392, which incorporates SPD's proposed findings of fact and C&D's responses. If a party did not oppose a proposed finding of fact with an appropriate record citation, and if that unopposed proposed finding of fact was supported by an appropriate record citation, the Court deemed that fact admitted and incorporates such unopposed facts as factual findings of the Court.

[3] To the extent that any finding of fact reflects a legal conclusion, it shall to that extent be deemed a conclusion of law, and vice versa.

A. The Parties

C&D and SPD are direct competitors in the U.S. market for home pregnancy tests. PPF ¶ 1. C&D's leading home pregnancy test brand, First Response, has been the market leader for many years, and SPD's leading brand, Clearblue, has been First Response's primary competitor. PPF ¶ 1.

B. The Reproductive Cycle

To understand this case requires a basic understanding of the reproductive cycle. The typical menstrual cycle lasts 28 days and is marked by two key events: the menstrual period and ovulation. Patrizio DT ¶ 6; Barnhart DT ¶ 9. The latter is the release of a ripe egg (or ovum) from the ovary. Patrizio DT ¶ 6; Barnhart DT ¶ 9. The time from the last menstrual period ("LMP") to ovulation, known as the follicular phase of the menstrual cycle, is generally two weeks, but variance in the length of the follicular phase can be "significant." Barnhart DT ¶ 9; Patrizio DT ¶ 6. The time from ovulation to the next menstrual period, known as the luteal phase of the menstrual cycle, is two weeks and is subject to much less variance than the follicular phase. Barnhart DT ¶ 9; Patrizio DT ¶ 10.

For a successful pregnancy to proceed, the following steps must take place. First, either through sexual intercourse or assisted reproductive technology, sperm must fertilize an egg within 24 hours of ovulation because a ripe egg can survive outside the ovary for only about 12 to 24 hours. Patrizio DT ¶ 7; Barnhart ¶ 8. In the case of sexual intercourse, fertilization may occur several days after intercourse, but it will not occur more than one day after ovulation. Tr. 396:13-16; *see also* Tr. 218:10-14; Patrizio DT ¶ 7; Barnhart DT ¶ 8. Second, the fertilized egg, now referred to as a blastocyst, must travel down the fallopian tube to the uterus. Patrizio DT ¶ 7. Third, the blastocyst must adhere to the endometrium (part of the lining of the uterus), a process called implantation, which occurs approximately six to nine days after ovulation. Patrizio DT ¶ 8. Once implantation occurs, the blastocyst begins secreting human chorionic

gonadotropin ("hCG"), a hormone that, among other things, signals to a woman's body that she is pregnant and prevents menses. Patrizio DT ¶ 8; Barnhart DT ¶ 34.[4]

Home pregnancy tests, including SPD's Clearblue brand and C&D's First Response brand, determine whether a woman is pregnant by detecting the presence (or absence) of hCG—the hormone released following implantation—in urine. PPF ¶ 2; Barnhart DT ¶ 4.

C. The Multiple Methods Used to *Determine* Pregnancy Duration

Prior to advances in modern medicine, doctors had only one way to determine a woman's estimated date of delivery: the date of her LMP, which occurs, on average, 40 weeks prior to delivery. PPF ¶ 6; Barnhart DT ¶ 10; PTX 50 at 2; PTX 51 at 1; PTX 121; DTX 121 at 1. Before the development of more advanced medical technology, such as ultrasound, a woman's LMP provided the most readily available and reliable estimate of pregnancy duration, which is also known as gestational age. Barnhart ¶¶ 10-11; PTX 50 at 2; PTX 51 at 1. One of the disadvantages of using LMP for determining pregnancy duration is that it assumes a standard 28-day menstrual cycle and that ovulation occurs on day 14; as noted, the follicular phase of the menstrual cycle is prone to vary. PTX 50 at 2; PTX 51 at 1; Barnhart DT ¶ 13. In addition, women often have a poor recollection of their LMP. PTX 50 at 2; PTX 51 at 1, 3. These two shortcomings mean that an estimate based on LMP may provide an inaccurate prediction of the date of delivery. *See, e.g.*, Barnhart DT ¶ 13; PTX 50 at 2; DTX 113 at 2; DTX 114 at 1.

Ultrasound technology provides doctors with a more sophisticated way to determine pregnancy duration, and it is now "standard practice to take an ultrasound scan of the developing fetus about 8 to 12 weeks after the reported LMP." Barnhart DT ¶ 14; Tr. 132:24-133:1; PTX 51 at 3. An ultrasound scan is used to measure a fetus's crown-rump length, which, using a formula, can be converted into an estimate of "embryonic age" (the number of weeks that have passed since fertilization). Tr. 444:4-12, 133:2-9, 918:18-919:2; PTX 51 at 3; DTX 121 at 4-5. Because fertilization occurs, on average, two weeks after a woman's LMP, a woman's estimated

[4] If the blastocyst does not travel down to the uterus it may adhere to the lining of the fallopian tube, which will cause an ectopic pregnancy; such blastocysts will secrete hCG even though a successful pregnancy will not result. Tr. 1251:16-1252:1; Patrizio DT ¶ 57.

date of delivery is generally 38 weeks after fertilization. Patrizio DT ¶ 24; Tr. 830:9-11, 832:2-9, 918:20-919:2; DTX 121 at 1; PTX 50 at 2. Although ultrasound results are more accurate, "the date of the LMP is usually the only piece of data available in very early pregnancy to determine gestational age; therefore, it remains the most commonly used method for estimating [gestational age] and assigning a due date." PTX 51 at 1; Barnhart DT ¶¶ 10-11.

Finally, in the context of in vitro fertilization, doctors have an additional method to determine pregnancy duration: the date of embryo transfer. PTX 50 at 2-3; DTX 121 at 9. In such contexts, doctors retrieve an egg from a woman, fertilize it, and then wait either three or five days to replace the embryo in the woman's uterus. Tr. 179:22-180:11; Patrizio RT ¶ 12-13; PTX 50 at 2-3. Thus, "for a day-5 embryo, the [estimated date of delivery] would be 261 days from the embryo replacement date. Likewise the [estimated date of delivery] for a day-3 embryo would be 263 days from the embryo replacement date." PTX 50 at 3; Tr. 439:1-440:24.

D. The Standard Convention for *Expressing* Pregnancy Duration

Although there are multiple ways to determine a woman's estimated date of delivery, and thus the duration of her pregnancy, there is a separate issue of how to express it—i.e., what words to use to describe "how far along" the pregnancy is. And on this point, which is the point that truly matters for resolution of this case, there is little genuine dispute. Doctors and others use a standard convention to *express* pregnancy duration. It is stated in terms of the number of weeks since a woman's LMP. Patrizio DT ¶¶ 11-13, 22; Barnhart DT ¶¶ 10-11, 24; Patrizio RT ¶¶ 2-3; Tr. 182:7-10, 197:4-23, 238:1-11, 265:1-4, 266:11-267:4, 277:17-21, 830:1-831:4, 833:11-834:22, 837:4-9, 1271:7-9, 1261:5-1261:12; PTX 1 at 3; PTX 2; PTX 50 at 1; PTX 51 at 1; PTX 52 at 1; PTX 53 at 10; PTX 54 at 11; PTX 55 at 5; PTX 121 at 1; PTX 149 at 3-4. As SPD's medical expert, Dr. Kurt Barnhart, testified: "While doctors have long known that women are not, and cannot be, pregnant at their LMP because ovulation does not occur, on average, for another two weeks, LMP has continued to be a reference point because, until relatively recently, it was either impossible or impractical to estimate when ovulation occurred." Barnhart DT ¶ 11. He further noted that "[e]ven after the advent of ultrasound scanning technology, the methods for

estimating when ovulation (and hence fertilization) occurred were generally intrusive, expensive, and/or impractical, and obviously could not be self-administered by a woman at home prior to becoming pregnant." Barnhart DT ¶ 11. Thus, for both historical and practical reasons, dating a woman's pregnancy from her LMP has been and remains a widely used method for determining pregnancy duration. But more importantly, it has continued to be the standard—indeed, universal—convention for expressing pregnancy duration. Barnhart DT ¶ 11; PTX 50 at 2; PTX 51 at 1; PTX 55 at 5; PTX 121.

In fact, even when pregnancy duration is determined using other methods, such as ultrasound scans, most medical professionals still convert to the LMP convention when communicating pregnancy duration to patients and other medical providers. Tr. 175:1-176:6, 238:24-239:9, 837:4-9; Patrizio DT ¶¶ 11-14; Patrizio RT ¶ 15. Ultrasound machines are even programmed to automatically convert an estimate of embryonic age based on crown-rump length into an estimate of pregnancy duration based on weeks since LMP. Tr. 175:7-11; PTX 55 at 5. As noted, in some cases, a woman may not recall the date of her LMP or her recollection may be inconsistent with an estimate based on an ultrasound scan. Even in these cases, "doctors typically will date the pregnancy according to the ultrasound results, but they will (by convention) express the duration of pregnancy in terms of the time since LMP would have been expected to occur in a normal menstrual cycle." Patrizio DT ¶ 12; Patrizio RT ¶ 9; Tr. 175:1-176:6. Similarly, in the context of in vitro fertilization, the embryonic age based on the date of embryo transfer is converted into an estimate of pregnancy duration in terms of weeks since LMP. Patrizio DT ¶ 13-14; Tr. 168:3-10, 179:22-182:10. In short, while doctors may have multiple ways to arrive at the convention—e.g., LMP, ultrasound, date of embryo transfer—they use a standard and uniform convention for expressing pregnancy duration: weeks since LMP.

That there is a single convention is unsurprising as it allows patients, doctors, and other healthcare providers to use the same metric for scheduling testing and other appointments during the course of pregnancy. PPF ¶ 6; Patrizio DT ¶ 11; Tr. 240:19-241:2, 830:12-18, 831:15-22, 835:15-836:13. Dr. Kurt Barnhart, SPD's expert witness, explained, "as we're moving forward

in a pregnancy, we want to make sure we're using the same standard so when we set a due date we're not – we're all working on the same convention and the same scale." Tr. 831:15-22.

Moreover, pregnant women have traditionally relied on their doctors for an estimate of pregnancy duration. Feldman RT ¶ 4; *see also* Tr. 479:23-25, 1184:5-10; PTX 100 at 5; PTX 121 at 1; PTX 149 at 4; DTX 37 at 1. SPD's suggestion that women could figure this out on their own based on their "own awareness of when they ovulated, had intercourse, and other relevant facts" combined with knowledge drawn from "myriad sources of information in books and on the internet regarding pregnancy dating," Dkt. No. 372 ¶ 6 (citing Daly ¶¶ 15-16, 42 & n.7-10), is unpersuasive and does not change the fact that historically doctors have been the authoritative source of information for women to find out how many weeks pregnant they are. Indeed, as described below, the FDA required SPD to include the following statement on all product advertising: "Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression." PTX 3 at 4; PTX 1 at 3.

E. The Clearblue Advanced Pregnancy Test with Weeks Estimator

Unlike other pregnancy tests, which merely tell a woman whether she is pregnant, SPD's Weeks Estimator also provides an estimate of the number of weeks that have passed since fertilization. PPF ¶ 5. To explain, the blastocyst begins producing hCG after fertilization, but hCG levels are not detectable in a woman's urine until there is contact between the blastocyst and the woman's body (usually at implantation in the uterus but sometimes as a result of an ectopic pregnancy). PPF ¶ 2; Patrizio DT ¶ 57; Tr. 1251:16-1252:1. These hCG levels rise rapidly and predictably during early pregnancy and can be used to estimate the number of weeks that have passed since fertilization. PPF ¶ 5. And because fertilization occurs within 24 hours of ovulation, the date of fertilization provides a proxy for the date of ovulation (and vice versa). Barnhart DT ¶ 8; Patrizio DT ¶ 7; Tr. 915:15-18.

Like other home pregnancy tests, then, the Weeks Estimator uses the presence or absence of hCG in the urine to tell a woman if she is pregnant. But if she is pregnant, the Weeks Estimator also uses the level of hCG in the urine to provide an estimate of how many weeks have

passed since ovulation. When a woman uses the product, a digital screen on the device will tell her if she is "Pregnant" (or "Not Pregnant"), and, depending on her hCG level, the screen will provide a result showing "1-2," "2-3," or "3+"—meaning, she is pregnant and it has been 1-2, 2-3, or 3+ weeks since ovulation. PPF ¶ 5.

F. The FDA Clearance Process

Home pregnancy tests are subject to FDA regulation as Class II medical devices. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *8-11; *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *6-8. Under 21 U.S.C. § 360(k), more commonly known as the "510(k) process," a party seeking to market a Class II medical device must submit to the FDA "a description of the device and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is 'substantially equivalent' to a pre-existing device.'" *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *6-7 (quoting *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *10). "A finding of substantial equivalence means the device 'has the same technological characteristics as the predicate device' or 'has different technological characteristics and . . . is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device.'" *Id.* at *14 (quoting 21 U.S.C. § 360c(i)(1)(E)(ii)(III)). If the FDA identifies "a use of the device not identified in the proposed labeling," however, it can still approve the device but with limitations on the device's labeling; "[t]he resulting clearance from the FDA is known as SE [substantial equivalence] with limitations." *Id.* at *14 (citations and internal quotation marks omitted).

In August 2012, the FDA issued a "Hold Letter," PTX 149 at 3-11, for SPD's 510(k) application because it had identified a potential concern with the Weeks Estimator's product labeling, i.e., its packaging. *Id.* at *11-12. Specifically, the FDA noted that the "weeks indicator feature may provide misleading information to lay population of users" largely because "the output of this test is not aligned with gestational aging done by healthcare professionals (i.e., it will under-estimate gestational age by an average of 2 weeks)." *Id.* (quoting PTX 149 at 3-4);

PPF ¶ 23. In light of this concern, the FDA required SPD to modify the "Indications for Use" statement on product packaging to include the following additional language:

> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that can not be substituted for a doctor's determination of gestational age.

Id. at *12-13 (quoting PTX 149 at 4). The Hold Letter also requested changing the product's name from "Conception Indicator," which led SPD to propose, and the FDA to accept, "Weeks Estimator." *Id.* at *13. The Hold Letter made a number of other requests, including, among other things, removing the statement "*Also Tells You How Far Along You Are*" from every area of the box. *Id.* at *13-14 (citing PTX 149 at 5). Following additional back-and-forth communications between SPD and the FDA, the FDA issued a "Clearance Letter" for the Weeks Estimator, which allowed SPD to begin marketing the product consistent with the FDA's directives as described in the Clearance Letter. *Id.* at *14-15. Among other things, the FDA instructed SPD (1) not to express the product's results as "weeks pregnant" and (2) to express the results only as "the number of weeks that may have passed since ovulation." PPF ¶ 14.

G. The Launch Advertising

In August 2013, SPD commenced an ambitious marketing campaign for the Weeks Estimator that was touted as the largest advertising expenditure in this product category. Tr. 1073:19-1074:10; PTX 100 at 7. Despite FDA's warnings, internal SPD marketing documents described the "communication idea" for this campaign as: "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator gives women the reassurance of knowing much more of their pregnancy because it is the only test that can also tell you how far along you are." PTX 209 at 9. In line with this strategy, and as described below, the Weeks Estimator's launch advertising consistently communicated the message that the product estimates "weeks pregnant," "weeks along," and similar ideas, while downplaying (or omitting) the message that the product provides an estimate of weeks since ovulation or that the product's estimate of "weeks" does not align with how a doctor would express an estimate of weeks pregnant.

1. The Launch Package

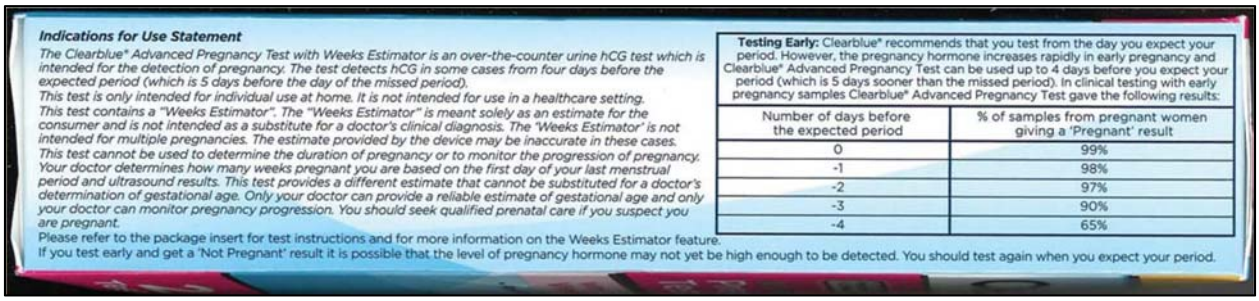
The launch package for the Weeks Estimator was on store shelves from August 2013 to February 2014. Daly DT ¶ 65. At the top left-hand corner of the box, "Clearblue" appears in large blue font, and on the top right-hand corner the word "NEW" appears against a yellow strip. PTX 3 at 2. In the middle left-hand side of the box the following words appear on four separate lines: "ADVANCED // Pregnancy Test // with Weeks Estimator // Results 5 DAYS Sooner." PTX 3 at 2. To the right of this language are four gray squares resembling digital screens with the following words inside them: "Pregnant // 1-2 Weeks"; "Pregnant // 2-3 Weeks"; "Pregnant // 3+ Weeks"; "Not Pregnant." PTX 3 at 2. To the right of the four gray squares there is an image of the actual product. PTX 3 at 2. In the lower left-hand corner of the box there is small white font stating: "See side of pack for details." PTX 3 at 2. The lower right-hand side of the package also contains an image of a white caduceus. PTX 3 at 2. The back panel is identical to the front panel; the only difference is that the back panel is arranged vertically while the front panel is arranged horizontally. PTX 3 at 1-2. The word "ovulation" does not appear anywhere on the front or back of the box. PTX 3 at 1-2. (An image of the front of the Launch Package is pasted below as Figure 1.)

Figure 1

The box contains two side panels with additional information. One side panel contains, in very small, cramped font (in a space that is 1.5 inches by 4 inches), the full FDA-required Indications for Use statement:

> *The Clearblue® Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).*
>
> *This test is only intended for individual use at home. It is not intended for use in a healthcare setting.*
>
> *This test contains a "Weeks Estimator." The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. The "Weeks Estimator" is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.*
>
> *This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.*

PTX 3 at 4; PTX 425. Just below the Indications for Use statement, there is a sentence asking consumers to "[p]lease refer to the package insert for test instructions and for more information on the Weeks Estimator feature." PTX 3 at 4. The word ovulation appears only on the top of the box in an image promoting an entirely different Clearblue product called the "Advanced Ovulation Test." PTX 3 at 5. (An image of the side panel containing the Indications for Use statement is pasted below as Figure 2.)



Indications for Use Statement

The Clearblue® Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).
This test is only intended for individual use at home. It is not intended for use in a healthcare setting.
This test contains a "Weeks Estimator". The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. The 'Weeks Estimator' is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.
This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.
Please refer to the package insert for test instructions and for more information on the Weeks Estimator feature.
If you test early and get a 'Not Pregnant' result it is possible that the level of pregnancy hormone may not yet be high enough to be detected. You should test again when you expect your period.

Testing Early: Clearblue® recommends that you test from the day you expect your period. However, the pregnancy hormone increases rapidly in early pregnancy and Clearblue® Advanced Pregnancy Test can be used up to 4 days before you expect your period (which is 5 days sooner than the missed period). In clinical testing with early pregnancy samples Clearblue® Advanced Pregnancy Test gave the following results:

Number of days before the expected period	% of samples from pregnant women giving a 'Pregnant' result
0	99%
-1	98%
-2	97%
-3	90%
-4	65%

Figure 2

2. The Television Commercial

From August 28, 2013 to December 2, 2013, SPD ran a nationally televised commercial promoting the Weeks Estimator (the "Television Commercial"), Daly DT ¶ 70, which aired thousands of times on at least 65 different networks and was projected to reach millions of women aged 18-49 each month, PPF ¶ 60. The Television Commercial shows two women sitting around a kitchen table engaging in the following dialogue:

1st Woman: I'm pregnant.
2nd Woman: Really?
1st Woman: Two weeks.
2nd Woman: You already went to the doctor?
1st Woman: Not yet, but I took this new Clearblue test. It's like two tests in one.
2nd Woman: Oh my God, I think I'm going to cry!

PTX 5-6. As the first woman says "It's like two tests in one," an image of the Weeks Estimator appears on screen with the digital screen prominently displaying "Pregnant // 1-2 Weeks.*" PTX 5-6.[5] After the second woman says, "I think I'm going to cry," the commercial cuts to an image for two seconds showing three large digital screens (containing the words "Pregnant // 1-2 weeks," "Pregnant // 2-3 weeks," and "Pregnant // 3+ weeks") in an arc over an image of the product with the phrase "ESTIMATED WEEKS SINCE OVULATION (UP TO 3+)" in grayish blue font below the arc and above an image of the product. PTX 5-6. As this screen is displayed, a voiceover says: "The new Clearblue pregnancy test also estimates how many weeks. Weeks Estimator. Only from Clearblue." PTX 5-6. Beginning at 6 seconds into the commercial and continuing to the end of the 15-second commercial, small white font appears at the bottom of the screen stating:

> *Word 'weeks' on display is for illustration only. For home use only. Always consult a doctor if you suspect you are pregnant and to confirm, date and monitor pregnancy. Not for multiple pregnancies. Estimates weeks since ovulation up to 3+ weeks. Do not use to monitor pregnancy progress or duration.

PTX 5-6.

[5] An image of this screen is pasted below as Figure 4 in Section III.A.3.a.

3. Other Launch Advertising

Prior to and after the launch of the Weeks Estimator, SPD maintained a dedicated webpage promoting the Weeks Estimator. Feldman DT ¶¶ 47-50; PTX 17. The top of the webpage displays the Clearblue logo next to the phrase: "The ONLY Pregnancy Test that Estimates Weeks." PTX 17 at 1. Just below that banner, the webpage prominently states "NEW! Pregnancy Test with Weeks Estimator," with an image of the product showing "Pregnant // 1-2 weeks" in the digital display window. PTX 17 at 1. The first prose script on the webpage is a paragraph stating:

> Clearblue® Advanced Pregnancy Test with Weeks Estimator is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks. It's like 2 tests in 1! This is the latest innovation in home pregnancy testing providing information that you can trust. Knowing more helps you prepare for the exciting future ahead – 78% of women surveyed said they believe it is important to know how far along they are.

PTX 17 at 1. Just below this paragraph, the webpage has a line break with an additional paragraph; the third sentence of that paragraph states: "It uses two separate testing strips to estimate how many weeks based on time since ovulation (1-2 weeks, 2-3 weeks, 3+ weeks)." PTX 17 at 1.

SPD also hired a celebrity spokesperson, Tamera Mowry-Housley, of "Sister, Sister" fame, to appear as a guest on the television show "The Doctors" to promote the Weeks Estimator. Suarez DT ¶¶ 2-6. After announcing that she and her husband are planning to have a baby, she says: "I am the new spokesperson for Clearblue. It's the pregnancy test. I am. I can't wait to use it . . . because it actually estimates how many weeks of pregnancy you're in." PTX 10. SPD contends that Ms. Mowry-Housley spoke "off script" and was not authorized to make this statement, Suarez DT ¶ 6, but internal emails reveal that SPD's marketing firm was "beyond pleased with how well this pitched placement delivered," PTX 269; Tr. 773:3-16.

In addition, SPD promoted the Weeks Estimator through a number of other channels, including presentations made to retailers, internet advertising (e.g., web banners), retailer circulars, retailer websites, and in-store advertising (e.g., side-wing displays and shelf trays).

PPF ¶ 63-64; PTX 18-24, 100, 215-216. These advertisements similarly convey the message that the product estimates "weeks pregnant" without any indication that this estimate differs from a doctor's estimate. *See, e.g.*, PTX 19 (Walgreens advertisement stating: "How Far Along Am I?" "Clearblue® Advanced Pregnancy Test with Weeks Estimator tells you in words if you are pregnant, and estimates how many weeks by measuring the pregnancy hormone level."); PTX 18 (point-of-sale displays stating "First pregnancy test to estimate weeks" and "How far along are you?"); *see also* Tr. 1070:1-1071:5 (noting that the shelf display messages shown in PTX 18 were designed to sit next to each other).

H. The Revised Advertising

As described in detail in the Court's March 24, 2015 Memorandum and Order, following complaints from C&D, the FDA reached out to SPD with concerns about its launch advertising. *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *15-16. For example, the FDA stated that it had informed SPD "not [to] talk about weeks pregnant" and "[p]lacing 'weeks' in the result window is the same as saying weeks pregnant." PTX 412; Tr. 344:14.

SPD then submitted a "mitigation proposal" to address some of the FDA's concerns. *Id.*; *see also* DTX 17; Tr. 354:4-355:5. In response to FDA objections to the Television Commercial, SPD proposed, among other things, adding language to the disclaimer and removing dialogue about a doctor's visit. DTX 017 at 3. The FDA found these changes insufficient, noting that even with the proposed changes the commercial

> still does not convey the limitations of [the] Week Estimator completely, nor does it clearly state that the device can only estimate weeks since ovulation (and not weeks of pregnancy) and therefore does not present a balanced and accurate description of [SPD's] product to customers. Further . . . [SPD is] required to communicate a complete and unmodified (i.e., unparaphrased) Indication For Use (IFU) statement in all of [its] promotional materials.

DTX 17 at 4. SPD also requested 10 days to take down the Television Commercial, but the FDA required it to do so in 6. DTX 17 at 4. Based on other feedback from the FDA, SPD revised the product's package and made a number of other changes to its advertising as described below.

1. Revised Package

The Revised Package began appearing on store shelves in February 2014. Daly DT ¶ 65. The front of the box is substantially similar to the Launch Package but with two key differences. First, in the top right-hand corner, instead of a yellow strip with the term "NEW," there is a gray strip with the phrase: "Only Test That // Estimates Weeks // Since Ovulation*." PTX 4 at 2. This phrase is separated onto three lines, with "Estimates Weeks" in larger, bold lettering on the middle line. Second, the digital screens to the right of "Advanced Digital[6] // Pregnancy Test // With Weeks Estimator" contain only the words "Pregnant // 1-2"; "Pregnant // 2-3"; "Pregnant // 3+"; and "Not Pregnant." PTX 4 at 2. Just below these four digital screens is the phrase "Weeks Along." PTX 4 at 2. On the side panel, the Indications for Use statement now appears with an asterisk in front of it—an apparent reference to the asterisk appearing after the phrase "Only Test That Estimates Weeks Since Ovulation*" on the front of the box. PTX 4 at 3. Otherwise, this and the other side panel are the same as the Launch Package. PTX 4 at 3-4. (An image of the front of the Revised Package is pasted below as Figure 3.)

Figure 3

[6] "Digital" appears after "Advanced" as opposed to under the digital screens in the Launch Package.

2. Internet-Only Commercial

As noted, SPD ceased airing the Television Commercial at the FDA's direction and replaced it with an Internet-Only Commercial, which is substantially similar to the Televised Commercial but with the following modifications. PTX 9. First, the dialogue is changed as follows:

1st Woman:	I have something to tell you: I'm pregnant!
2nd Woman:	Really?
1st Woman:	I took this Clearblue test. It's like two tests in one.
Voice over:	Only Clearblue tells you if you are pregnant and estimates how many weeks since ovulation.
2nd Woman:	Oh my God, I think I'm going to cry!
Voice over:	Weeks estimator, only from Clearblue.

PTX 9. During the voice over, the commercial cuts to the same image of the three large digital screens (with "Pregnant // 1-2," "Pregnant // 2-3," and "Pregnant // 3+") in an arc over an image of the product with the phrase "ESTIMATED WEEKS SINCE OVULATION (UP TO 3+)" in grayish blue font below the arc and above the product. PTX 9. Following this image, the commercial cuts to an image of the Revised Package in the center of the screen with "Weeks Estimator" in large, pink lettering jumping out of the box, distracting the eye from the rest of the packaging. PTX 9. The commercial ends with the full Indications for Use statement on screen for 15 seconds, but this is the only disclaimer that appears during the commercial. PTX 9.

3. Other Revised Advertising

SPD replaced the original webpage for the Weeks Estimator in December 2013 with a new webpage. Daly DT ¶ 78. The new webpage is substantially similar to the old webpage, but with the following modifications: (1) the image of the Launch Package has been replaced with an image of the Revised Package; (2) the word "New" no longer appears on the page; (3) and the word "weeks" no longer appears in the digital screen for the Weeks Estimator. DTX 173. In addition, the first paragraph of prose script on the webpage has been modified to read:

> Clearblue® Advanced Pregnancy Test with Weeks Estimator is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks since ovulation. It's like 2 tests in 1! This is the latest

> innovation in home pregnancy testing providing information that you can trust. Knowing more helps you prepare for the exciting future ahead.

DTX 173. That is, "since ovulation" was added following "number of weeks," and the phrase "78% of women surveyed said they believe it is important to know how far along they are" was deleted.

I. SPD's Intentional Deception

As discussed in the conclusions of law, Lanham Act jurisprudence soundly presumes that consumers are in fact deceived if an advertiser sets out to deceive them. Based on the facts set forth in the following paragraphs, the Court finds that SPD's staff engaged in such intentional deception prior to and after the launch of the Weeks Estimator. Time and again, SPD's staff recognized and understood that the Weeks Estimator's result did not align with how doctors express pregnancy duration and that this misalignment could confuse consumers. Rather than clarify its product advertising, SPD's staff sought to exploit the confusion.

To begin with, SPD's staff were fully aware that the medical community uses a standard convention for expressing pregnancy duration based on the number of weeks since a woman's LMP, whether actual or conventionalized (i.e., using a standard follicular phase of two weeks). PPF ¶ 8; *see also* PTX 122 at 1. For example, in a peer-reviewed article analyzing the use of hCG to estimate the date of fertilization, Dr. Sarah Johnson, SPD's Head of Clinical and Medical Affairs, observed that "[h]istorically, pregnancy is dated using the first day of the last menstrual period (LMP)." PTX 51 at 1. Similarly, a report that SPD submitted to the FDA as part of the 510(k) process recognized that "[t]raditionally, gestational age has been estimated from a woman's recollection of her LMP. . . . Standard clinical practice dictates that gestational age determined by ultrasound is also extrapolated to an estimated LMP date." PTX 55 at 5.[7]

Consistent with these pre-trial statements, SPD's witnesses acknowledged at trial—often with considerable reluctance—the existence of the LMP convention. After one such longwinded

[7] Similarly, many studies that SPD offered into evidence reference the convention for dating pregnancy based on weeks since LMP. *See, e.g.*, DTX 113 ("Pregnant woman are routinely assigned a delivery date of about 280 days after the onset of their last menstrual period.").

explanation, the Court pointedly asked Dr. Joanna Pike, SPD's Senior Global Pregnancy Product Manager, "If someone says to you or you read somewhere I am four weeks pregnant without any further explanation, what would you assume that means?" Tr. 1184:2-4. Dr. Pike, withdrawing deeper into her chair, provided a convoluted answer before finally acknowledging that "I think in general you may – you may – this, it is time since LMP because it is widely used," which she hesitantly admitted was "[t]he truth." Tr. 1184:22-1185:3. The truth it was.

To his credit, when asked on cross-examination if he "kn[ew] the convention used by medical doctors to date pregnancy," Mark Gittins, SPD's Chief Compliance Officer, provided one of the few straightforward answers on this topic: "The convention is to date pregnancy from the first day of last menstrual period." Tr. 265:1-4. He further acknowledged that the product in issue provides an estimate that differs from how a doctor expresses pregnancy duration. Tr. 277:22-25.

Aware of the convention, SPD staff members recognized that the Weeks Estimator's result was likely to confuse consumers. For example, Dr. Pike provided the following analysis in an email to her colleagues:

> We should not suggest in US that the product tells you 'Weeks Pregnant' when we have been constrained by FDA to say 'weeks since ovulation'. Indeed, even outside of US, this product doesn't tell you weeks pregnant – if you are 1-2 weeks by [the Weeks Estimator] then you are 3-4 weeks pregnant because the universal convention for dating pregnancy is from the LMP not from ovulation. . . . I think FDA would NOT approve if we used 'Weeks Pregnant' in any materials and we are very likely to also confuse consumers and might end up with challenge/complaint.

PTX 52 at 1. At trial, Dr. Pike first attempted to escape the plain meaning of these words by arguing that she was conveying the FDA's views, not her own. Pike DT ¶ 7. The email considered as a whole—particularly the statement that the convention for dating pregnancy is from LMP even outside the FDA's jurisdiction—belies this explanation. In her cross-examination, Dr. Pike also tried to explain the final sentence about consumer confusion as "using a bit of hyperbole here because [she] was very strongly trying to kill" an advertising mockup showing a baby "bump" she did not like. Tr. 1166:17-1167:15. Based on her tone, demeanor,

and unconvincing explanations, the Court found Dr. Pike's attempt to contradict the plain meaning of her email lacking credibility. Her email was candid. Her testimony about the email was not.

In addition to its own staff, members of SPD's U.S. Advisory Board, which was created "[t]o allow SPD to obtain external expert advice on product strategy and launch plans," PTX 53 at 6, also highlighted the existence of the LMP convention and the possible confusion that might result from the discrepancy between the product's estimate and a doctor's estimate based on the convention. For example, one Board member stated at an early meeting "that LMP was currently the pregnancy-related time measurement that most women understood and that pregnancies were dated from this point by obstetricians. He added that it was important not to contradict this clinician-defined measurement." PTX 53 at 10. At a subsequent meeting, another Board member raised concerns about the digital display screens containing "Pregnant 1-2," etc., noting: "Need to be clearer what this means, i.e. from time of conception NOT LMP, we are Not saying what we are doing." PTX 69 at 30; *see also* PTX 472 at 13 (Stewart Wilson Depo. Tr. 71:12-72:7). At yet another meeting, a different Board member "suggested that medical professionals are behind the time[s] when it comes to dating pregnancy using LMP" and that "there could be an opportunity to change the way doctors date pregnancy," but "there was acknowledgment that this would be a large undertaking." PTX 54 at 11.

Despite awareness of the LMP convention and warnings about confusion from the FDA, its in-house scientific staff, and its Advisory Board, SPD advertised the Weeks Estimator in ways that were intended to obfuscate the distinction between the Week's Estimator's result of weeks since ovulation and the estimate of pregnancy duration a doctor would provide.

Perhaps the most glaring example of this deceptive behavior revolves around the Television Commercial. Ryan Daly, Clearblue's Worldwide Marketing Director, acknowledged at trial that it would be untrue to "communicat[e] to consumers that this product can estimate weeks of pregnancy the same way that a doctor does, or would give the same result as a doctor." Tr. 715:18-716:5. Nonetheless, the very story board for the Television Commercial is entitled

"Before the Doctor Visit," PTX 238 at 2, Tr. 1170:2-7, and an internal SPD PowerPoint presentation described the Television Commercial as "Best Friends with the insight of knowing it before the doctor visit," PTX 209 at 10. Unsurprisingly, SPD's market research revealed that viewers believed the product can tell you how far along you are before you go to the doctor, PTX 110 at 8; PTX 111 at 13-19; Tr. 1062:22-1065:1, which, as discussed in greater detail below, necessarily implies that the product will provide the same estimate one would get *from* a doctor's visit.

Prior to airing the advertisement, Mr. Daly explained to his colleagues that "I know we are being told by some that the FDA will be waiting for this ad, but I really struggle with that given their setup . . . they have a pharma ad division but none for [over-the-counter products]. Net, I view the risk as low." PTX 211 at 1. In other words, he thought the likelihood of getting caught airing an ad that contravened FDA requirements was minimal because the FDA did not have resources to police advertising for over-the-counter products.[8] Instead, he was concerned the networks would get cold feet about the product's ability to substantiate its advertising message:

> To me the thing that keeps me up at night is network clearance. Particularly around the area of replacing your Dr … Now I think the copy does a great job of not pushing this as a replacement to Dr, and our supers will cover us, but some could get shy should they read the entire intended for use statement. So for this, I think we need to be very careful … I want us to see everything that we plan to send the TV stations. Only give them what they ask for.

PTX 211 at 1 (ellipses in original). (To obtain clearance to air a commercial on network television, advertisers are typically required to submit "substantiation" for the commercial's advertising messages. PPF ¶ 35.) At trial, Mr. Daly provided a farfetched explanation[9] for this

[8] The FDA ultimately did object to the Television Commercial, noting it "conveys the message that the Weeks Estimator product can be used for measuring the number of weeks of pregnancy and pregnancy progression because of the dialogue between the 2 women ('I'm pregnant. 2 weeks. You already went to the doctor? Not yet.'), whereas the Indications for Use statement includes the following limitation: 'This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy'. Therefore the TV commercial may be misleading to a consumer who may understand the device measures pregnancy progression and duration." PTX 136 at 2.

[9] Mr. Daly's lack of credibility revealed itself repeatedly, from his description of something referred to internally as the "Bedford puke," PTX 211 at 1, an apparent shorthand for the dangers of providing too much

email, unconvincingly stating that it expressed his concern about overwhelming the networks with too much information: "We have technical people who will sometimes provide hundreds of pages of information when you only really need one page." Tr. 718:3-8. Rather than give the networks the full Indications for Use statement, which is less than a page long, SPD gave the networks a substantially truncated version that omitted the warning: "Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that can not be substituted for a doctor's determination of gestational age." Tr. 719:8-720:15. It was also the truncated version of the Indications for Use statement that was used as a "super" (disclaimer text at the bottom of the screen), and that Mr. Daly believed would "cover" SPD. And when asked where in the commercial it communicates the message that the product's estimate is different from a doctor's estimate, Mr. Daly answered: "Again, you're looking at one medium, and when you actually have a pack that a consumer can potentially pick up in great detail, it discusses the, you know, the fact that this is a different method. We also call attention to our website at the end of the ad to provide further information. I think you can't just take it – you know, you can't take one specific execution and sum up what someone would take away from that." Tr. 712:4-11.

Unfortunately, Mr. Daly was not the only SPD staff member who exhibited such disregard for truthful advertising. Anticipating a likely complaint from the FDA or C&D regarding the Television Commercial, SPD's staff discussed creating a backup commercial that correctly identified a key problem with the ad: "Back up plan is Best Friends with no mention of 'knowing before doctor visit.'" PTX 209 at 12; PTX 257 at 1; Tr. 761:8-763:7; *see also* PPF ¶ 37. Kirsten Suarez, Clearblue's Brand Manager, similarly surmised: "Is our guess that First Response would challenge the doctor portion so we're solving for that? Can we not wait to receive a letter and then edit? I'm guessing we'd have time between receipt of the letter and actual need to traffic in new copy/pull from the networks." PTX 257 at 1. The Court finds that

information to regulators and broadcasters, Tr. 720:16-721:22, to his statement that SPD prepared shelf trays that "were shipped to one single retailer," Daly DT ¶ 81, which just happened to be Target, Tr. 1066:8-19; 1067:4-12.

these communications show that SPD staff knew precisely what was false or misleading about the commercial, but they chose to air it anyway. At trial, Ms. Suarez unconvincingly explained: "I thought the fact that we included a doctor was good because we wanted to ensure that women still got prenatal care, and here we are showing her still going to the doctor." Tr. 763:2-7.

Ms. Suarez also made other troubling statements about the Weeks Estimator's advertising that suggest a deliberate attempt both to evade FDA limitations and convey a false message about the product. For example, she made the following statement about promotional materials developed for CVS: "One last thing, we can't actually link together the weeks and pregnant in the way it was on the last couple. What you can say is the only test that estimates weeks, or the only test that also estimates weeks, then the consumer will see Pregnant 1-2 Weeks in the windows and put it together." PTX 214 at 1. This statement also reveals that SPD's staff knew that placing the word "pregnant" in proximity to "weeks" would suggest that the product provides an estimate of weeks pregnant.[10] In another email, Ms. Suarez recognized that SPD could not advertise the product as estimating "how far along," but that it could refer to survey results indicating that women want to know how far along they are because "[w]e can't say we're doing it, just that women want to know." PTX 260 at 1. In yet another email she responded to a suggestion that an advertisement should say "Find out how far along you are," with the following: "This is a tricky one, but the FDA doesn't actually want us to say that. I think it can be phrased as a question as you had, or we need to use the 'estimate weeks' language." PTX 358 at 4-5.[11]

SPD staff also believed that consumers did not have a good understanding of ovulation. For example, in response to Dr. Pike's suggestion that consumers know what ovulation is, Ms. Suarez replied: "Trust me, it doesn't really make sense to them. The other slides in that deck

[10] The FDA shared the same view: "In the letter we say you should not talk about weeks pregnant. Placing 'weeks' in the result window is the same as saying weeks pregnant." PTX 412 at 1.

[11] Ms. Suarez also explained that she was not concerned that consumers would misinterpret the advertising as suggesting that the product provides the same estimate of weeks pregnant as a doctor because "it actually didn't seem like that big of a deal to me." Tr. 802:23-24.

show how they don't have a knowledge of the right days, poor understanding of the details, etc. and it's not common vernacular of how we would talk anything." PTX 62 at 2.[12] She subsequently stated: "Ryan/I/our PR agency/US team doesn't want to talk 'ovulation' other than when we have to, like on a graph, because people do not connect that to when they got pregnant." PTX 62 at 1; Tr. 751:5-25, 756:17-757:5; *see also* PTX 259 at 4; Tr. 1257:8-11. Similarly, a summary of a meeting between Dr. Johnson and colleague Fiona Humberstone with SPD's outside marketing firm discussing the product's advertising contains the heading: "Why doesn't weeks estimate match my doctor's estimate?" PTX 59 at 2. Under that heading, it is noted that "[t]he data doctors use [is] measured from last menstrual period (LMP) whereas our data measures since the egg was fertilized," and "[o]verall lack of consumers' understanding of ovulation may cause confusion. Need to address the reason why [healthcare providers] use different method without saying it is wrong or suggesting that Weeks Estimator takes the place of seeing [a healthcare provider]." PTX 59 at 2. Thus, although SPD did eventually add the word "ovulation" to its advertising, these communications reveal why SPD did not want to use ovulation in the launch advertising and why it downplayed ovulation in the revised advertising.

Attempting to counter the evidence that it set out to intentionally deceive consumers, SPD repeatedly suggested that it had tried in vain to include a conversion chart on the outside of the product's packaging that would mitigate consumers' confusion regarding how the product's estimate of weeks differs from a doctor's estimate of weeks pregnant. To begin with, SPD provided a shifting reason for the absence of the conversion chart. SPD initially stated in its brief in support of its motion *in limine* to dismiss all false advertising claims that the FDA "prohibited" or "forbade" it from "placing the LMP/ovulation conversion chart on the outside of the box." Dkt. No. 224 at 21 n. 9; *see also* Dkt. No. 232 at 9. By the time of SPD's pre-trial briefing, its contention that the FDA forbade placing the chart on the outside of the box had softened into an explanation that SPD "*understood* the FDA's instruction to remove 'accuracy'

[12] The "deck" referred to is a PowerPoint presentation admitted as PTX 61.

information from the outside of the box to require removal of all performance information concerning the estimation of weeks function, including the Conversion Chart." Dkt. No. 307 ¶ 34 (emphasis added). Finally, at trial, Dr. Johnson stated that it was only after doing a "deep" read of the Clearance Letter that SPD's staff determined that they had to remove the conversion chart from the outside of the package. Tr. 1194:16-23, 1203:17-24; *see also* Johnson DT ¶ 28 (interpreting Hold Letter). Because SPD often overstated other instances of the FDA and broadcasters "requiring" or "mandating" as opposed to "permitting" or "allowing" certain conduct, *compare* Daly DT ¶ 72, *with* Tr. 700:13-705:20, the Court does not credit SPD's explanation for the removal of the conversion chart. Similarly, it is not at all clear from the FDA's Hold and Clearance Letters that the FDA intended to prohibit SPD from including the conversion chart on the outside of the box. *See, e.g.*, DTX 1 at 5.

Moreover, while SPD frequently pushed back against the FDA regarding other changes that it did not like, it did not ask the FDA to clarify whether the FDA actually wanted SPD to remove the conversion chart, nor did it object to the removal based on concerns that the conversion chart was needed to avoid consumer confusion. Instead, SPD relied on its own claimed interpretation of the FDA's communications to decide that it had to remove a conversion chart that it now argues would have mitigated consumer confusion regarding its product. SPD also failed to offer any alternative suggestions to the FDA to retain the primary message of the conversion chart in other forms. Regardless, SPD's own staff were concerned about confusion *even with* the conversion chart on the outside of the package: Dr. Pike's assessment that putting "weeks pregnant" on the product's packaging was likely to confuse consumers—because it did not align with the "universal" convention for pregnancy dating—was made in the context of assuming that the chart would be "readily visible" on the package. PTX 52; Tr. 1194:24-1198:9.

In sum, SPD was aware that the Weeks Estimator's result did not align with the standard convention for dating pregnancy; SPD was warned by the FDA, its U.S. Advisory Board, and in-house scientific staff about the possibility of consumer confusion; and yet SPD developed

advertising that was intentionally designed to mislead consumers about the difference between the product's estimate of weeks since ovulation and a doctor's estimate of weeks pregnant.[13]

J. What the Court Is Not Deciding

Before addressing its conclusions of law, the Court takes this opportunity to note a factual finding that it is not making: when pregnancy begins "as a biological matter" (to use SPD's terminology). Although the parties spent much time pursuing this red herring—with experts testifying on behalf of SPD that pregnancy begins at fertilization and on behalf of C&D that it begins at implantation—the Court concludes that even if this were a factually answerable question, it need not decide it because it has little, if any, bearing on the key legal issues in this case. The key issue is whether SPD's advertising communicates the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant and, if so, whether this message is false. When pregnancy begins "as a biological matter" is, therefore, beside the point.

III. CONCLUSIONS OF LAW

As described above, doctors use a standard convention for expressing pregnancy duration based on weeks since a woman's LMP. SPD's Clearblue Advanced Pregnancy Test with Weeks Estimator tells a woman if she is pregnant and provides an estimate of weeks since a woman last ovulated. Under the Lanham Act, the Court must determine whether SPD's advertising conveys the false message that the product provides an estimate of weeks that is consistent with a doctor's estimate of weeks pregnant. Based on its findings of fact and conclusions of law, the Court concludes that it does and that C&D is entitled to injunctive relief. The Court also concludes, however, that C&D failed to present sufficient evidence to establish its claim for breach of contract.

[13] SPD's intentional deception extended to other aspects of its advertising not directly relevant here, such as touting the fact to U.S. retailers that 15% of European purchasers of the product had used the product to track their pregnancy despite the FDA's explicit restrictions on making such statements. PTX 117; Tr. 1085:21-1091:2.

A. False Advertising under the Lanham Act[14]

Stated succinctly, the elements of a Lanham Act claim require a plaintiff to demonstrate that the defendant's advertising message[15] (1) is false, either literally or impliedly, (2) is material, and (3) causes or is likely to cause injury to plaintiff. *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255 (2d Cir. 2014) ("*Merck Eprova II*").[16] Due to the complexity of the doctrine, the Court briefly elaborates the legal standard necessary to satisfy each of these elements.

Starting with the first element, falsity may be premised on one of two theories: (a) the advertising is "literally false as a factual matter," or (b) it is impliedly (i.e., misleadingly) false, which means that, "although the advertisement is literally true, it is likely to deceive or confuse consumers." *Id.* (quoting *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001)). To establish literal falsity, a plaintiff must show that (i) the advertisement makes an express statement of falsity (i.e., it is "false on its face") or (ii) the advertisement is "false by necessary implication," meaning the advertisement's "words or images, considered in context, necessarily and unambiguously imply a false message." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 148, 158 (2d Cir. 2007). If "an advertising [message] is literally false, the court may enjoin the use of the [message] without reference to the advertisement's impact on the buying public." *Merck Eprova II*, 760 F.3d at 256 (quoting *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010)). But if an advertising message is impliedly false, a plaintiff generally must show evidence of consumer confusion, unless there is evidence that the defendant intended to deceive the public through "deliberate conduct" of an "egregious nature," in which

[14] C&D also brought a claim for false advertising under Section 349 of New York's General Business Law, which the parties agree imposes the same liability standard as the Lanham Act. *See* Dkt. No. 308 at 6; Dkt. No. 291 at 72 n.15; Dkt. No. 368 at 15 n.4; Dkt. No. 371 at 6.

[15] In many Lanham Act cases, the parties and courts often refer to the messages or statements in the challenged advertising as "claims," i.e., claims about what the product does. But using "claim" for an advertising statement or message is unnecessarily confusing in light of the legal usage of "claim," which generally means "[t]he aggregate of operative facts giving rise to a right enforceable by a court" or "[t]he assertion of an existing right; any right to payment or to an equitable remedy, even if contingent or provisional." *Black's Law Dictionary* 281-82 (9th ed. 2009). To avoid confusion, the Court uses the term "message" in lieu of "claim."

[16] The statute also requires proof that the allegedly false advertising was placed in interstate commerce, 15 U.S.C. § 1125(a), which, as a practical matter, is rarely contested.

case "a presumption arises that 'consumers are, in fact, being deceived.'" *Id.* (quoting *Johnson & Johnson * Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298-99 (2d Cir. 1992)).

Furthermore, only unambiguous messages can be literally false. *Time Warner*, 497 F.3d at 158. Thus, as a practical matter, the court must first determine whether the challenged advertising conveys an unambiguous message, either by express statement or necessary implication; if so, the Court must determine whether that message is literally false. But if the advertising does not convey an unambiguous message, the Court generally must look to consumer surveys to determine what message is conveyed to consumers and then determine whether the message conveyed is false. *Id.*

Turning to the second Lanham Act element, materiality, the Second Circuit requires a plaintiff to show that "the defendants misrepresented an inherent quality or characteristic of the product." *Merck Eprova II*, 760 F.3d at 255 (citing *S.C. Johnson*, 241 F.3d at 238).

Finally, for liability as opposed to damages, the third element—injury—turns on "whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980) (citing *Parkway Baking Co. v. Freihofer Baking Co.*, 255 F.2d 641, 649 (3d Cir. 1958); *Ames Publ'g Co. v. Walker-Davis Publ'ns, Inc.*, 372 F. Supp. 1, 13 (E.D. Pa. 1974); 2 J.T. McCarthy, *Trademarks and Unfair Competition* § 27:5 at 249-50 (1973)).

1. Launch Package

Beginning with the Launch Package, the Court concludes that the package's advertising message is unambiguous and literally false. And even if the message were ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception and, furthermore, it has shown evidence of consumer confusion.

a) Literal Falsity

As noted, a piece of advertising need not make an express statement of falsity to be literally false under the Lanham Act; rather, "[i]f the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." *Time Warner*, 497 F.3d at 158 (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Pharm., Co.*, 290 F.3d 578, 586-87 (3d Cir. 2002)). Although the Launch Package does not make an express statement that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant, the Launch Package's words and images, considered in context, necessarily imply this unambiguous message, which is false.

First, the Court concludes that the Launch Package, considered in context, necessarily implies an unambiguous message. Considered together, the name of the product ("Clearblue Advanced *Pregnancy* Test with *Weeks* Estimator") and the digital screens ("*Pregnant* // 1-2 *Weeks*," etc.), without any clarification, necessarily imply that the product tells a woman whether she is pregnant and, if she is pregnant, how many weeks pregnant she is. Moreover, the Weeks Estimator is a home pregnancy test—i.e., an over-the-counter medical device—that is marketed to women for use before they see a doctor about their pregnancy, and women have historically relied on their doctors for an estimate of pregnancy duration. Thus, in the context of a home pregnancy test that also provides an estimate of "weeks," the overriding message to consumers is that this is an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. *Cf. Avis Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381, 384-85 (2d Cir. 1986) (Friendly, J.) ("[T]he evidence pointed unmistakably to an interpretation that Hertz was speaking of cars available for rental and not of total cars owned. Hertz and Avis have made their reputation as companies that *rent* cars, not companies that sell or merely own cars."). A caduceus in the lower right-hand corner of the box augments this message.[17]

[17] The caduceus is a conventionalized symbol of the medical profession. *See Webster's Third New Int'l Dictionary* 312 (1961) (defining caduceus as "a conventionalized representation of a staff with two snakes curled around it and with two wings at the top" and as "one of the symbols of a physician").

Second, the Court concludes that this unambiguous message is false. Because doctors use a standard convention for expressing pregnancy duration based on weeks since a woman's LMP, while the Weeks Estimator provides an estimate of weeks since ovulation, the message that the product provides the same estimate of weeks pregnant as a doctor is false.

SPD's attorneys and witnesses devoted considerable energy to evading, downplaying, or refusing to acknowledge the existence of the standard convention for expressing pregnancy duration. These efforts to avoid acknowledging the existence and import of a standard convention—one that even its own staff described as "universal"—do not suffice to render its advertising truthful; indeed, other courts have rejected similar attempts to evade the import of words bearing a conventional meaning in a given context. *See Johnson & Johnson v. GAC Int'l, Inc.*, 862 F.2d 975, 982 (2d Cir. 1988) ("A word that has no meaning except that which is assigned to it cannot be untrue. But where, as here, a 'coined' word incorporates words that do have preexisting meanings and connotations, we see no reason to allow any greater leeway for deceptiveness."); *Merck Eprova AG v. Gnosis S.p.A.*, 901 F. Supp. 2d 436, 453 (S.D.N.Y. 2012) ("*Merck Eprova I*") ("[W]hile the Court found Dr. Siegel to be credible, his testimony was largely irrelevant to this action, as it spoke to a theoretical use of the contested terms that bordered on the aspirational, not to how those terms are actually used. . . . But, even if *some* terms are misused, he ultimately did not dispute that these terms are consistently used in the way Merck contends they should be." (citations omitted)).

SPD also argues that the Launch Package cannot convey a message that is false by necessary implication because of the Indications for Use statement on the side of the package. But the entire statement is 206 words long, separated into four paragraphs, and printed in minuscule font. Stacey Feldman, C&D's Vice President of Marketing for Women's Health and Personal Care, credibly testified that in her experience very few consumers will read the Indications for Use statement on the side panel, Feldman DT ¶¶ 20-21, and even Ryan Daly, Clearblue's Worldwide Marketing Director, testified that "the statement in its entirety on the pack [is] fairly long," hence why he opted to provide what he considered to be a shorter, "more

consumer-friendly version" to the broadcasters, Tr. 709:8-13. Moreover, as many courts have found, "[a] footnote or disclaimer that 'purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims.'" *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 906 F. Supp. 178, 182 (S.D.N.Y. 1995) (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 590 (S.D.N.Y. 1987)). Stated differently, a lengthy disclaimer on the side of a box that is unlikely to be noticed by consumers cannot remedy advertising "that necessarily conveys a false message to the consumer." *Novartis Consumer Health, Inc.*, 290 F.3d at 598.

Similarly, SPD routinely pointed to the package insert for the product as eliminating any possibility of consumer confusion. The same disclaimer points discussed above apply to this insert. Moreover, the Court finds SPD's argument unpersuasive for two additional reasons. First, the product is wrapped in cellophane plastic so the package insert is not available to the consumer until the consumer has purchased the product and, therefore, the Lanham Act injury is complete by the time the consumer reads the package insert. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *40 n.6. Second, the Court agrees with Ms. Feldman's observation that "many consumers will not review with care most of the information contained in the Package Insert," which is "particularly likely because SPD's extensive advertising campaign will have already deceived many consumers who purchase the Weeks Estimator to believe that it will tell them how long they have been pregnant, and the digital readout of the results on the Product test stick will not appear to such consumers to require interpretation." Feldman DT ¶ 16.

b) Implied Falsity

Alternatively, even if the Launch Package's advertising were ambiguous, the Court concludes that the Launch Package is impliedly false; that is, it is "likely to mislead or confuse consumers." *Time Warner*, 497 F.3d at 153 (citing *Coca-Cola v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982)). "'[P]laintiffs alleging an implied falsehood are claiming that a

statement, whatever its literal truth, has left an impression on the listener [or viewer] that conflicts with reality'—a claim that 'invites a comparison of the impression, rather than the statement, with the truth.'" *Id.* (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999)).

As noted above, because the Court finds that SPD intentionally set out to deceive consumers and that this conduct was of an egregious nature, C&D is entitled to a presumption "that consumers are, in fact, being deceived." *Merck Eprova II*, 760 F.3d at 256 (quoting *Smithkline Beecham Corp.*, 960 F.2d at 298-99). In such cases, "the burden shifts to the defendant to demonstrate the absence of consumer confusion." *Id.* Having failed to come forward with any evidence demonstrating an absence of consumer confusion, SPD has not rebutted this presumption. Thus, C&D satisfies its burden of demonstrating that the Launch Package deceives consumers.

But even if C&D had not come forward with evidence of SPD's intentional deception, C&D has provided evidence of both actual confusion and likelihood of confusion. First, C&D introduced an April 2014 news report from the CBS affiliate in Los Angeles, California, reporting that an expectant mother who had purchased the Launch Package believed the product provided an estimate of weeks pregnant that was consistent with how her doctor would estimate weeks pregnant. PTX 120. The woman became concerned, wondering if her "baby was not developing correctly," when her doctor told her that she was further along in her pregnancy than the estimate provided by the product. PTX 120.[18] SPD's public relations agency brought the news story to SPD's attention, but it recommended that SPD "make no proactive statement at this time and let the story fade away." PTX 226A at 2. In response, Procter & Gamble's Communications Manager for Personal Health Care suggested the following: "My thinking is

[18] SPD did not object to this exhibit when it was admitted into evidence. Tr. 458:2-17. However, SPD appeared surprised that the exhibit was already in evidence when it was discussed at a later stage of trial, Tr. 1092:1-1093:2, suggesting it intended to object to the exhibit, which it never did. Even if the hearsay objection were not waived, C&D did not offer the exhibit for the truth of the matter asserted, Tr. 1092:15-:1093:2, and the Court is not relying on it for this purpose.

that we make the confusion a story, and how we're helping bring pregnancy testing into the 21st century with better science, so good that it's helping doctors reframe 'the way they've always done it?'" PTX 226A at 1. Despite this suggestion, SPD did nothing to address the confusion. Tr. 1097:1-21.

C&D also pointed to approximately 340 complaints made to SPD's consumer "care line" as examples of consumer confusion. PTX 65-67; Patrizio DT ¶ 67.[19] However, of these, only 30 were from consumers located in the United States and only 17 reflect that the complaining consumer mistakenly believed that the product estimates pregnancy duration the same way a doctor would. Sammel DT ¶ 11; Patrizio DT ¶ 50, 67; PTX 65-67. Because the present lawsuit concerns only U.S. advertising, the 310 non-U.S. complaints have little bearing on this case. In addition, the Court agrees with SPD that 30 complaints represents a small percentage when compared to the roughly 1,866,215 Weeks Estimators sold to U.S. consumers from August 2013 to June 2014. Cristobal DT ¶ 7. At the same time, the Court does not agree with SPD that the small number of complaints demonstrates an absence of confusion because many deceived consumers may not even know about the care line or may not be inclined to call it. In short, although these few consumer complaints are evidence of actual confusion, they are of modest weight.[20]

Second, C&D presented evidence of likelihood of confusion in the form of Hal Poret's consumer surveys, which focused on the Weeks Estimator's Launch and Revised Packaging. For the Launch Package, Mr. Poret concluded that 19.0% or 21.9% (depending on the base used)

[19] SPD objected to the consumer complaints on relevance and hearsay grounds, and the Court indicated that it would admit the exhibits for what they may be permissibly considered for. *See* Dkt. No. 335 at 143; Tr. 120:7-12. It is unclear from SPD's objections to C&D's proposed findings of fact whether it maintains this objection. *See* PPF ¶ 77. In any event, the objection is overruled because the consumer complaints are not offered to prove that the Week's Estimator does or does not estimate pregnancy duration the same way a doctor would; they are offered only to show the declarant's—i.e., the consumer's—state of mind. *See Fun-Damental Too v. Gemmy Indus. Corp.*, 111 F.3d 993, 1003-04 (2d Cir. 1997) ("The testimony in question was not offered to prove that Fun-Damental was actually selling to some retailers at lower prices, but was probative of the declarant's confusion.").

[20] C&D also pointed to comments made on social media, such as Facebook, as examples of actual consumer confusion. SPD countered that the comments are inadmissible and/or unreliable. Because of the other available evidence of consumer confusion, the Court need not determine whether the social media comments are admissible or, if admissible, how much weight they should be given.

of participants answered both that the product estimates the number of weeks a woman is pregnant and that the product's estimate of weeks is the same as a doctor's estimate of weeks pregnant. Poret DT ¶ 106. Mr. Poret explained that this is a conservative figure, i.e., favorable to SPD, because he "assumed that a respondent was deceived only if that respondent answered *both* that the Product estimates the number of weeks a woman is pregnant and that the Product's estimate of weeks is the same as a doctor's." Poret RT ¶ 61. Even this conservative figure reveals that a substantial number of participants understood the Launch Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with the estimate a doctor would provide. *See Merck Eprova AG v. Brookstone Pharm., LLC*, 920 F. Supp. 2d 404, 419-20 (S.D.N.Y. 2013) (finding 11% is a "substantial percentage"). As noted above, this message is false.

Using a scattershot approach, SPD criticized Mr. Poret's survey on myriad grounds—from the survey population he used to the design of his questions to the way he coded his answers. "The evidentiary value of a survey depends on its underlying objectivity as determined through many factors, such as 'whether [the survey] is properly "filtered" to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive.'" *Novartis Consumer Health, Inc.*, 290 F.3d at 591 (quoting *SmithKline Beecham Corp.*, 960 F.2d at 300). Bearing this standard in mind, and upon a careful review of Mr. Poret's testimony, consideration of how he fared on cross-examination, and based as well on the testimony of SPD's survey expert, Sarah Butler, the Court concludes that Mr. Poret's survey is reliable and that SPD's criticisms are meritless.

In sum, the Court concludes that C&D has established Lanham Act liability with respect to the Launch Package on multiple grounds: (1) the Court concludes that the Launch Package necessarily implies an unambiguous message that is false; (2) in light of SPD's intentional deception, C&D is entitled to a presumption, which SPD did not rebut, that the Launch Package in fact deceives consumers; and (3) the Launch Package is misleadingly false in light of the evidence of (a) actual confusion and (b) likelihood of confusion.

2. Revised Package

As noted above, the only differences between the Revised and Launch Package are the insertion of "Only Test That Estimates Weeks Since Ovulation*," the removal of "weeks" from the digital screens, and the insertion of "Weeks Along" just below the digital screens. PTX 4 at 2. Both parties pointed to competing evidence regarding the degree to which consumers do or do not understand the meaning of "ovulation" and its relationship to how a doctor dates pregnancy, and thus the degree to which adding "since ovulation" to the front of the box would clarify that the Weeks Estimator provides an estimate that does not align with a doctor's estimate. The Court need not resolve this dispute—and thus, the Court need not determine whether adding "since ovulation" alters the package's unambiguous message—because it concludes that, regardless, the Revised Package is impliedly false.

As a preliminary matter, it is unclear from the case law whether C&D is entitled to the presumption of consumer confusion as to all of SPD's advertising based on SPD's intentional deception that is directly tied to only specific pieces of advertising. On the one hand, an advertiser who has learned the error of its ways and has modified its advertising accordingly should not be forever held to account for prior instances of bad conduct. On the other hand, evidence of prior intentional deception may be probative of whether subsequent corrections were sincerely implemented. The Court notes, for example, that even though SPD added the phrase "since ovulation" to the Revised Package, this phrase is not displayed prominently, which is consistent with SPD's internal emails stating that it did not want to use the word "ovulation" in relation to the Weeks Estimator because "US women do not have a clear enough understanding of ovulation." PTX 59; *see also* PTX 62 (SPD's marketing team "doesn't want to talk 'ovulation' other than when we have to, like on a graph, because people do not connect that to when they got pregnant.").

Regardless of whether C&D is entitled to the presumption of consumer confusion based on SPD's intentional deception, C&D presented evidence that this Court found persuasive of likelihood of consumer confusion based on Mr. Poret's surveys. For the Revised Package, Mr.

Poret concluded that 16.0% or 17.3% (depending on the base used) of participants answered both that the product estimates the number of weeks a woman is pregnant and that the product's estimate of weeks is the same as a doctor's estimate of weeks pregnant. Poret DT ¶ 106. Thus, Mr. Poret's survey reveals that a substantial number of participants understood the Revised Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate. As noted, this message is false.

3. Television Commercial

Turning to the Television Commercial, as with the Launch Package, the Court concludes that the commercial's advertising message is unambiguous and is literally false. And even if the message were ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception and, furthermore, it has shown evidence of consumer confusion.

a) Literal Falsity

The Court has little difficulty concluding that the Television Commercial necessarily implies an unambiguous message that is false. Although the Television Commercial does not make an express statement that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate, the Court finds that this is the clear takeaway from the commercial. As with the Launch Package, the proximity of the words "weeks" and "pregnant" in the digital screens and the repeated message that the product is a home pregnancy test that also provides an estimate of "weeks" ("The new Clearblue *pregnancy* test also estimates how many *weeks*") suggest in the overall context of the commercial that the product provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. The dialogue between the two women only further augments this unambiguous message when the first woman states that she knows she is two weeks pregnant despite not having gone to the doctor yet because she used the Weeks Estimator. This exchange communicates to the viewer that the woman received the same estimate of weeks pregnant from the product that she would have received had she gone to the doctor—which is false.

SPD argues that the "super," or disclaimer, at the bottom of the screen combined with the phrase "Estimated Weeks Since Ovulation," which appears for two seconds at the bottom of the screen showing the arc of digital screens, makes the commercial literally truthful or, at a minimum, ambiguous. However, SPD intentionally omitted language from the super clarifying that the estimate of pregnancy duration from a doctor is different from the Weeks Estimator's result. Moreover, the super at the bottom of the screen is in small, whitish font that blends in to the white background such that even the Court failed to notice it upon first viewing. (An image of the screen shot containing this disclaimer is pasted below as Figure 4.) The phrase "Estimated Weeks Since Ovulation" at the bottom of the chart, which appears for two seconds, is similarly inconspicuous. As noted above, such inconspicuous disclaimers are insufficient to offset the overriding message of the advertisement.

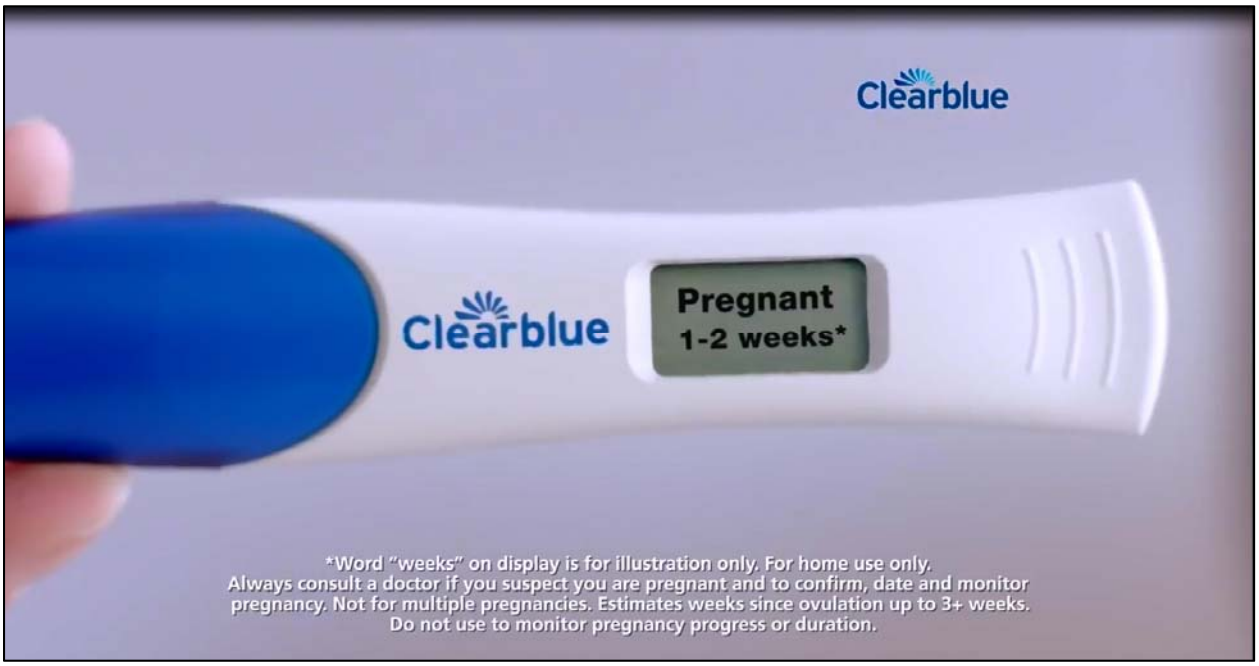


Figure 4

b) Implied Falsity

Even if not false by necessary implication, the Television Commercial is misleadingly false. As with the Launch Package, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception, exemplified by Mr. Daly's and Ms. Suarez's emails and

testimony regarding the Television Commercial. SPD failed to come forward with any evidence that consumers are not misled by the Television Commercial, thus the Court presumes that the commercial deceived consumers.

C&D also presented evidence of likelihood of consumer confusion based on Dr. Bruce Isaacson's consumer surveys, but the Court need not rely on this evidence in light of the Court's finding that the Television Commercial is literally false and that SPD engaged in intentional deception regarding the Television Commercial.

4. Other Advertising

Finally, the Court concludes that much of the other advertising C&D cited is just as literally false as the Launch Package. The webpage prominently asserts that the product "is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks." PTX 17. The paragraph on the initial webpage concludes by noting that "78% of women surveyed said they believe it is important to know how far along they are." PTX 17. Without any other qualification, and given the context, the necessary implication is that this product provides an estimate of weeks pregnant that is consistent with a doctor's estimate. Similarly, courts have recognized that false advertising made in the context of presentations to retailers falls within the Lanham Act's ambit. *See, e.g.*, *Symantec Corp. v. CD Micro, Inc.*, No. 02-406-KI, 2003 U.S. Dist. LEXIS 25608, at *8 (D. Or. Feb. 3, 2003) ("The important point is that the misrepresentations must be made to an entity who purchases plaintiff's product, not whether that entity is the ultimate consumer."). And the presentations made to retailers as well as internet advertising (e.g., web banners), retailer circulars, retailer websites, and in-store advertising (e.g., side-wing displays, shelf trays) convey the message that the product estimates "weeks pregnant," which, in context, conveys the message that the estimate is the same as a doctor's estimate of weeks pregnant. *See, e.g.*, PTX 19 (Walgreens advertisement stating: "How Far Along Am I?" "Clearblue® Advanced Pregnancy Test with Weeks Estimator tells you in words if you are pregnant, and estimates how many weeks by measuring the pregnancy hormone

level."); PTX 18 (point-of-sale displays stating "First pregnancy test to estimate weeks" and "How far along are you?").

To the extent this other advertising is ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception as reflected in, among other things, Ms. Suarez's emails discussed above.[21]

5. Materiality

The Second Circuit consistently applies a materiality standard that requires showing only "'that the defendants misrepresented an inherent quality or characteristic of the product.'" *Merck Eprova II*, 760 F.3d at 255 (quoting *S.C. Johnson*, 241 F.3d at 238); *see also Time Warner*, 497 F.3d at 153 n.3 ("Under either theory [of falsity], the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." (citing *S.C. Johnson & Son, Inc.*, 241 F.3d at 238; *NBA v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)); *Fur Info. & Fashion Council, Inc. v. E.F. Timme & Son, Inc.*, 501 F.2d 1048, 1051 (2d Cir. 1974) (stating Lanham Act Section 43(a) "was intended to apply only to misrepresentations relating to the inherent qualities of defendant's own goods").

The Weeks Estimator's ability to estimate weeks is, as the product's name conveys, an inherent quality or characteristic of the product as it is the key feature that differentiates it from the many other home pregnancy tests on the market. Indeed, much of SPD's marketing for the Weeks Estimator touted the message that it is the *only* pregnancy test with this feature. *See, e.g.*, PTX 17 (SPD's webpage stating "Clearblue® Advanced Pregnancy Test with Weeks Estimator is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks."); *see also* Tr. 1061:11-16; PTX 110 at 5, 7 (discussing consumer reaction to Television Commercial, noting: "The new weeks estimator feature piques her interest in the product and makes her want to try."). Such marketing strongly suggests that SPD itself believed that the weeks estimating feature was an inherent quality or characteristic of

[21] C&D's post-trial briefing did not contain any specific arguments regarding the Internet-Only Commercial, nor did it offer any evidence during trial of consumer confusion regarding the Internet-Only Commercial.

the product. *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 312 (1st Cir. 2002) ("It seems reasonable to infer from defendants' aggressive marketing strategy highlighting the 'cashmere' nature of the blazers that defendants themselves believed cashmere to be an inherent and important characteristic of the blazers."). For these several reasons, the Court concludes that the weeks estimating function, which SPD misrepresented, is an inherent quality or characteristic of the product.

6. Injury

A Lanham Act plaintiff must also show injury, but, for liability purposes,

> [t]he statute demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising. The correct standard is whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales.

Carter-Wallace, 631 F.2d at 190; *see also Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272, 278 (2d Cir. 1981) ("Although Sassoon offered no evidence of actual sales loss directly traceable to the alleged misrepresentations, proof of diversion of sales is not required for an injunction to issue pursuant to § 43(a)."). And, "[t]o prove a likelihood of injury[, plaintiff] must also show a logical causal connection between the alleged false advertising and its own sales position." *Id.* at 190; *see also Vidal Sassoon*, 661 F.2d at 278; *Brookstone Pharm., LLC*, 920 F. Supp. 2d at 429; *L & J. G. Stickley, Inc. v. Cosser*, No. 5:02-CV-1542, 2008 U.S. Dist. LEXIS 7463, at *10 (N.D.N.Y. Jan. 31, 2008); *Telebrands Corp. v. Media Grp*, No. 97 Civ. 6768 (RPP), 1997 U.S. Dist. LEXIS 20474, at *9 (S.D.N.Y. Dec. 24, 1997).

As an initial matter, "[i]n cases where, as here, the district court has found literal falsity, [the Second Circuit has] never required a finding of extrinsic evidence of injury to consumers or to the plaintiff." *Merck Eprova II*, 760 F.3d at 259. Because the Court finds that the Launch Package, Television Commercial, and comparable other advertising are false by necessary implication (i.e., literally false), C&D need not provide extrinsic evidence of injury.

But even if that were not the case, C&D provided evidence showing a logical causal connection between SPD's false advertising and its own sales position. From 2001 to 2011 First Response's market share (excluding sales at Wal-Mart) increased from 12.0 "dollar share points" (market share in terms of dollar sales) to 29.8 dollar share points in 2011. PTX 29; Feldman DT ¶¶ 62 n.11, 70. (Each dollar share point is equal to approximately $2.6 million in retail sales for C&D on an annual basis. Feldman DT ¶ 68.) And in the year and a half preceding the launch of the Weeks Estimator, First Response's market share across all outlets continued to grow from 28.8 dollar share points at the beginning of 2012 to 32.4 dollar share points in August 2013. PTX 28; Feldman DT ¶¶ 64-80. Clearblue's market share, in contrast, went from approximately 16 dollar share points at the beginning of 2012 to 12.5 dollar share points in August 2013. PTX 28; Feldman DT ¶¶ 64-80.

SPD then launched the Weeks Estimator in August 2013 with an extensive marketing campaign, budgeting over $30 million for advertising, which it boasted was the "highest marketing investment ever seen in the category." PPF ¶ 53. SPD described the goal of this large investment as follows: "enabl[e] Clearblue to attain a dominant share of voice leadership of 60% v. First Response 30% and ept (10%)," PTX 100 at 7, with the aim of becoming "the Pregnancy Test market leader behind this innovative launch. (we are currently the #2 brand behind First Response***)," PTX 100 at 3-4.

Although Clearblue did not replace First Response as the number one home pregnancy test brand in terms of dollar share points, it gained market share while First Response lost market share. Within three months of the product's launch, the Weeks Estimator went from 0 to 9 dollar share points, and the Clearblue brand as a whole gained 7.7 dollar share points to reach a total of 20.2 dollar share points. PTX 28; *see also* Feldman DT ¶ 62. First Response's market share, in contrast, declined 2.4 dollar share points during these three months and continued to decline to 29.7 dollar share points by January 18, 2014. PTX 28. Dr. Tulin Erdem credibly testified that

> [t]his sharp change in the market cannot be attributed to any feature of the Product besides the "weeks estimator" feature. First, the core of SPD's advertising for the Product was the promotion of the "weeks estimator" feature. Second, the other

> function of the Product – the detection of pregnancy – was unchanged from the Clearblue digital pregnancy tests that had long been on the market before the launch of the Weeks Estimator.

Erdem DT ¶ 62.

SPD's internal marketing documents similarly attributed Clearblue's market gain and First Response's market loss to its marketing campaign for the Weeks Estimator. *See, e.g.*, PPF ¶ 92; PTX 107, 102, 108, 109; Erdem DT ¶¶ 57-61. For example, a member of SPD's marketing team sent an email in September 2013 noting: "Great News – SPD and Clearblue set all-time share records in September behind the holistic marketing plan launch and is on track to deliver the year!" Erdem DT ¶ 58; PTX 107 at 1. And, as noted, the key message of this holistic marketing plan was that the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator gives women the reassurance of knowing much more of their pregnancy because it is the only test that can also tell you how far along you are." PTX 209 at 9; *see also* PTX 100 at 4-5 ("Advantage versus First Response and E.P.P.: delivers the only pregnancy test to also estimate the # of weeks' pregnant"; "Strategies: Drive trade-up by filling the unmet need to know # of weeks' pregnant"). Indeed, both parties conducted market research showing that consumers were attracted to the idea of a pregnancy test that could estimate weeks pregnant, *see* Feldman DT ¶¶ 58-59; PTX 25, 26, 112, 113, and that SPD's Television Commercial "was highly persuasive, and effective in motivating consumers to purchase the Product. In particular, '[t]he relevancy of the information regarding the weeks estimator accuracy' was found to be 'driving the desire for the target audience to purchase the product.'" Feldman DT ¶ 61 (quoting PTX 27 at 8, 70); *see also* PTX 26.

Despite this evidence, SPD argues that C&D failed to establish a logical causal connection between the Weeks Estimator's false advertising and C&D's sales position because it did not conduct the type of "rigorous" analysis—particularly regression analysis to control for a host of independent variables—that SPD believes is necessary. SPD's argument is more appropriate in the damages phase of this case and has little bearing on merits liability for injunctive purposes because C&D need only show a "logical causal connection" and need not

"come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales." *Carter-Wallace*, 631 F.2d at 190; *see also EFCO Corp. v. Symons Corp.*, 219 F.3d 734, 740 n.5 (8th Cir. 2000) ("Symons attacks Hancock's damage analysis for failing to account for all possible market forces. This criticism is more appropriate to a discussion of damages than causation, for it addresses what amount of EFCO's loss is attributable to Symons' conduct, rather than whether Symons[] caused the loss in the first instance."). In *Carter-Wallace*, for example, it was irrelevant for purposes of liability and injunctive relief "[t]hat much of the decline in Johnson's Baby Oil sales may be due to competition from lower priced baby oils" or "that the total pecuniary harm to Johnson might be relatively slight." *Id.* at 191. In any event, Dr. Erdem refuted most, if not all, of SPD's experts' hypothesized explanations for First Response's market decline.[22]

The Court finds SPD's other criticisms of Dr. Erdem's analysis equally unavailing. For example, Dr. Cox, one of SPD's expert witnesses, contends that "First Response did not experience a *significant* change in share of units sold at the time of the alleged false advertising." Cox DT ¶ 13 (emphasis added). But C&D need only show that it has been or is likely to be harmed, not that this harm is significant. In any event, at $2.6 million in annual sales per dollar share point, even the loss of just one dollar share point is significant in terms of revenue. And it is particularly significant in terms of relative market share given that C&D and SPD generally have only 20-30 share points each and bitterly compete with each other for *every* share point they have. Moreover, it is likely that C&D's countervailing actions, such as offering rebates and other promotions, mitigated the decline in its market share. Feldman DT ¶ 79; Tr. 583:8-584:4.

[22] For example, Dr. Cox argued that "Ms. Feldman testified that the Weeks Estimator had a price advantage over C&D's First Response products," Cox DT ¶ 26 (citing Feldman Dep. Tr. 268), and, therefore, "it is important to determine what portion of C&D's alleged decline was attributable to relative price and promotional pricing by SPD (digital and analog products) and other competitors," Cox DT ¶ 27. But, as Dr. Erdem testified, "Clearblue home pregnancy test kits have been priced lower than First Response pregnancy tests for the past several years when comparing digital to digital and analog to analog, and the Weeks Estimator is in fact more expensive than Clearblue's other home pregnancy test kits." Erdem RT ¶ 56. Moreover, after the launch of the Weeks Estimator, "First Response's relative price arguably continued to grow, but at a much slower rate than it had between March 2013 and July 2013." Erdem RT ¶ 57.

Dr. Cox also posited that because it was an exciting new product that was extensively advertised, the Weeks Estimator arguably grew the home pregnancy test market as a whole, suggesting that C&D should not complain about any decline in market share as its sales were larger than they would have been without the Weeks Estimator. Cox DT ¶ 28. This argument is unconvincing: Even if the whole pie grew because of the new product, but C&D's share of that pie grew at a smaller rate than it would have in the absence of SPD's false advertising, C&D would still have lost sales on account of the false advertising.

In short, the Court concludes that C&D established a logical causal connection between SPD's false advertising and its market harm that is sufficient to establish SPD's liability for false advertising under the Lanham Act, and it finds SPD's arguments to the contrary unavailing.

7. False Advertising Conclusion

In sum, C&D has successfully shown that SPD's advertising message is false, either literally or impliedly, is material, and causes or is likely to cause injury to C&D. The trial also reinforced the Court's prior observation that the Lanham Act and the FDCA complement each other, allowing the expertise, perspective, and resources of market competitors to augment those of the FDA. *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *16-29. As the discussion of SPD's intentional deception reveals, SPD considered the FDA's limited resources when weighing the risk of airing a deceptive television commercial—a fact the Supreme Court cited as a basis for rejecting FDCA preclusion and preemption arguments in *POM Wonderful*, 134 S. Ct. at 2239, and *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). Moreover, the trial confirmed that "competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators." *POM Wonderful*, 134 S. Ct. at 2238. The FDA had to make its decisions regarding the Weeks Estimator's labeling largely in advance of the product's launch, without the benefit of consumer surveys or other evidence of possible consumer confusion. C&D's Lanham Act suit brought this additional evidence to light and revealed the ways in which the product's

packaging causes consumer confusion. As previously noted, "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers." *Id.* at 2239.

B. Injunctive Relief

C&D asks the Court to permanently enjoin SPD from advertising the Weeks Estimator as providing an estimate of weeks that is consistent with a doctor's estimate of weeks pregnant. "Indeed, '[i]n most cases, after a full trial finding false advertising, a final injunction is appropriate.'" *Fresh Del Monte Produce Inc. v. Del Monte Foods Co.*, 933 F. Supp. 2d 655, 660 (S.D.N.Y. 2013) (quoting 5 J.T. McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:37 (4th ed. 2012)). Relatedly, C&D asks the Court to require SPD to undertake corrective advertising. To obtain a permanent injunction, a plaintiff must satisfy a four-factor test, which requires demonstrating

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). Because the "first and second factors in the *eBay* test often blend together," *Fresh Del Monte*, 933 F. Supp. 2d at 664, the Court addresses them together, but otherwise addresses each factor separately.

1. Irreparable Injury and Inadequacy of Damages at Law

"To demonstrate irreparable harm in a Lanham Act case, a party 'must show two things: (1) that the parties are competitors in the relevant market, and (ii) that there is a logical causal connection between the alleged false advertising and its own sales position." *CJ Prods. LLC v. Snuggly Plushez LLC*, 809 F. Supp. 2d 127, 149 (E.D.N.Y. 2011) (quoting *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, at *104-105 (S.D.N.Y. July 19, 1999)); *see also Coca-Cola Co.*, 690 F.2d at 316. "Harm might be irremediable, or irreparable, for many reasons, including that a loss is difficult to replace or difficult to measure,

or that it is a loss that one should not be expected to suffer." *Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010).

There is no dispute that the parties are direct competitors in the market for home pregnancy tests. PPF ¶ 1. And, as noted in Part III.A.6., C&D has established a logical causal connection between SPD's false advertising and its own sales position. Moreover, SPD's argument that C&D must control for numerous independent variables to account for every possible factor that may have affected its market share demonstrates the difficulty of fully quantifying the loss of market share that C&D suffered as a result of its direct competitor's false advertising.

Both parties also position themselves as "innovators" in the market for home pregnancy tests. Feldman DT ¶ 82. SPD falsely advertises the Weeks Estimator as offering an innovative feature that is highly attractive to consumers, which has likely increased consumers' perceptions of Clearblue as being more innovative than First Response. Erdem DT ¶ 98. Indeed, Clearblue's internal marketing documents reveal that it believed the Television Commercial, which the Court concludes conveys a false message, produced a "halo effect" for the Clearblue brand. PTX 111 at 1 ("I just received topline data which show great results for the TV copy! . . . 'Week estimator/can tell you how far along you are' is well recalled (67%) and identified as the main idea of the copy (58%). It generates high differentiation (88%) with a halo effect on the brand."); *see also* PTX 256 (discussing Television Commercial's halo effect); Tr. 758:10-759:13. SPD staff explained that a "halo effect" is the benefit conferred on the parent brand from positive advertising related to a product marketed under that brand. Tr. 758:18-759:8; *see also* Erdem RT ¶ 61 n.24. Thus, while innovation is a key distinguisher between the First Response and Clearblue brands, it is difficult if not impossible to quantify the harm to C&D caused by SPD's falsely advertising its product as possessing an innovative feature that it did not in fact possess.

Moreover, falsely advertising a product within a given category may cause harm to that category as a whole. Consumers who purchase the Weeks Estimator and then learn that it does not actually estimate weeks pregnant the way a doctor does may lose confidence in home

pregnancy tests as a whole and may question innovative features offered by other brands. *See, e.g., N. Am. Olive Oil Ass'n v. Kangadis Food Inc.*, 962 F. Supp. 2d 514, 518-19 (S.D.N.Y. 2013) ("In addition, Kangadis's labeling allegedly induces consumers to purchase a product that is not what it seems, and thus may cause consumers to lose faith in olive oil products in general. These types of harms are quintessentially irreparable, as '[i]t is virtually impossible to prove that so much of one's sales will be lost or that one's goodwill will be damaged as a direct result of a competitor's advertisement.'" (quoting *Coca-Cola*, 690 F.2d at 316)); *see also Tripledge Prods., Inc. v. Whitney Res., Ltd.*, 735 F. Supp. 1154, 1166 (E.D.N.Y. 1990). Therefore, the Court concludes that it will be difficult to replace or measure the harm to C&D's loss of market share, goodwill, and brand equity caused by SPD's false advertising.

2. Balance of Hardships

As extensively discussed above, the Court concludes that C&D has been and likely continues to be injured by SPD's false advertising, while SPD can claim no protected interest in its false advertising because parties cannot "assert an equitable interest in the perpetuation of an advertising campaign that is literally false." *Reckitt v. Benckiser Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446, 456-57 (S.D.N.Y. 2011) (citing *Zeneca*, 1999 U.S. Dist. LEXIS 10852, at *118). Moreover, when asked at trial if it would "be damaging to consumer confidence in the weeks estimator or the Clearblue brand for SPD to disseminate advertising stating clearly that the estimate that this product – that the estimate that the weeks estimator provides is different from a doctor's estimate of weeks of pregnancy," Mr. Daly avoided providing an answer. Tr. 1123:16-1125:4. SPD may, of course, continue to advertise its product, but it must do so in a way that is truthful and not misleading. *Zeneca*, 1999 U.S. Dist. LEXIS 10852, at *119.

3. Public Interest

"Finally, the Court must 'ensure that the public interest would not be disserved by the issuance of a preliminary injunction.'" *Juicy Couture, Inc. v. Bella Int'l, Ltd.*, 930 F. Supp. 2d 489, 505 (S.D.N.Y. 2013) (quoting *Salinger*, 607 F.3d at 80). On this point, "[t]he Second Circuit has long held that there is a 'strong interest in preventing public confusion.'" *Id.* (quoting

ProFitness Phys. Therapy Ctr. v. Pro-Fit Ortho. and Sports Phys. Therapy P.C., 314 F.3d 62, 68 (2d Cir. 2002)). The Court concludes that providing greater clarity in advertising an over-the-counter medical device would not disserve the public interest.

4. Unclean Hands

SPD previously asserted an unclean hands defense to C&D's request for injunctive relief. Dkt. No. 308 at 15-16. But SPD did not assert this defense in its post-trial brief and instead converted much of its unclean hands defense into an argument for attorney's fees, which is meritless in light of the Court's liability finding. Dkt. No. 371 at 34-35. Thus, it appears that SPD has abandoned its unclean hands defense, but, even if not abandoned, it is meritless.

5. Scope of Injunctive Relief

Based on the above analysis, the Court concludes that C&D is entitled to injunctive relief. Broadly speaking, SPD is permanently enjoined from communicating—either literally or impliedly—that the Weeks Estimator provides an estimate of weeks pregnant that is the same as a doctor's estimate of weeks pregnant. In light of the complexity surrounding such injunctive relief, however, the Court hereby orders the parties to meet and confer to see if they can reach agreement on the specific language of a permanent injunction order. *Accord Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 185 (S.D.N.Y. 2004) (directing parties to submit proposals for corrective advertising following finding of false advertising liability). To assist those discussions, the Court provides the following guidance.

First, as previously noted, injunctive relief in false advertising cases generally extends to the messages conveyed in the false advertising and is not limited to the specific pieces of advertising containing those messages. *Church & Dwight II*, 2014 U.S. Dist. LEXIS 158551, at *9-10 (citing *Am. Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 164 (2d Cir. 1978); *Santana Prods, v. Bobrick Washroom Equip., Inc.*, 249 F. Supp. 2d 463, 522-23 (E.D. Pa. 2003), *rev'd on other grounds*, 401 F.3d 123 (3d Cir. 2005)); *see also S.C. Johnson*, 241 F.3d at 241 ("Rule 65(d) does not require the district court to 'predict exactly what [Clorox] will think of next' or to describe all possible, permissible future commercials that Clorox may produce

involving Ziploc Slide-Loc storage bags." (quoting *Sterling Drug, Inc. v. Bayer AG*, 14 F.3d 733, 748 (2d Cir. 1994))). Therefore, the Court's determination that C&D is entitled to injunctive relief is not limited to the specific pieces of advertising presented to the Court, but extends as well to other forms of advertising that currently exist or that SPD may develop in the future.

Second, because the Court concludes that both the Launch and Revised packaging contain false advertising, SPD will be prohibited from marketing or distributing either the Launch or Revised packages in their current form and will be required to recall all Launch and Revised packages currently on store shelves. *Telebrands Corp. v. Wilton Indus.*, 983 F. Supp. 471, 477 (S.D.N.Y. 1997) (ordering recall of products containing false advertising); *Playskool, Inc. v. Product Dev. Grp., Inc.*, 699 F. Supp. 1056, 1063 (E.D.N.Y. 1988) (same). The Court has considered the burden and expense of such a recall, but finds it appropriate in light of the nature of the product, *Playskool*, 699 F. Supp. at 1063, as well as the degree of SPD's intentional deception.

Third, corrective advertising is often awarded in false advertising cases "to counteract the false impression that may have been placed by the ad in consumer's minds." *Linotype Co. v. Varityper, Inc.*, No. 89 Civ. 4747 (MJL), 1989 U.S. Dist. LEXIS 9105, at *8 (S.D.N.Y. Aug. 4, 1989); *see also Merck Eprova v. Gnosis S.P.A.*, No. 07 Civ. 5898 (RJS), 2013 U.S. Dist. LEXIS 49798, at *6 (S.D.N.Y. Mar 7, 2013) ("[C]ourts have long ordered defendants to engage in corrective advertising campaigns following their infliction of Lanham Act injuries."). In light of the legal and factual findings above, the Court will consider ordering SPD to engage in a corrective advertising campaign to explain the difference between the product's estimate of weeks since ovulation and a doctor's estimate of pregnancy duration based on weeks since LMP. *Merck Eprova I*, 901 F. Supp. 2d at 463; *Merck Eprova II*, 760 F.3d at 264.

With these points in mind, the parties shall submit a proposed permanent injunction order no later than three weeks from the date of this Opinion and Order. If the parties are unable to reach an agreement, C&D shall submit a proposed permanent injunction order and the parties shall submit letters no longer than three pages in length setting forth their respective positions

regarding the wording of the permanent injunction order. The Court will not entertain a rehashing of arguments previously made.

C. Breach of Contract

Finally, C&D also brought a claim for breach of contract against SPD based on a settlement agreement between the parties. "Under New York law, a breach of contract claim requires proof of (1) an agreement, (2) adequate performance by the plaintiff, (3) breach by the defendant, and (4) damages." *Fischer & Mandell LLP v. Citibank, N.A.*, 632 F.3d 793, 799 (2d Cir. 2011) (citing *First Inv. Corp. v. Liberty Mut. Ins. Co.*, 152 F.3d 162, 168 (2d Cir. 1998); *Harsco Corp. v. Segui*, 91 F.3d 337, 348 (2d Cir. 1996)). "[P]arties to an express contract are bound by an implied duty of good faith, but breach of that duty is merely a breach of the underlying contract." *Cruz v. Fxdirectdealer, LLC*, 720 F.3d 115, 125 (2d Cir. 2013) (quoting *Harris v. Provident Life & Accident Ins. Co.*, 310 F.3d 73, 80 (2d Cir. 2002) (internal quotation marks omitted). And, moreover, "New York law . . . does not recognize a separate cause of action for breach of the implied covenant of good faith and fair dealing when a breach of contract claim, based upon the same facts, is also [pleaded]." *Id.* (quoting *Harris*, 310 F.3d at 81) (internal quotation marks omitted).

First, C&D argues that SPD breached Section 2.7(ii) of the Settlement Agreement, which requires SPD to negotiate in good faith with C&D for 30 days after C&D provides written notice of a challenge to certain SPD advertising. PTX 33 at 7. Section 2.7(ii) also provides that "[d]uring the 30-day negotiation period, the advertising Party shall indicate whether it asserts that the challenged Advertising Claim is subject to one or more of the covenants-not-to-challenge provided for" in the Settlement Agreement. PTX 33 at 7. C&D provided SPD with written notice of its proposed challenge on August 23, 2013, PTX 34, and SPD responded on September 19, 2013, PTX 35. SPD's letter asserted that Section 2.5 of the Settlement Agreement barred C&D's challenge, but C&D complains that SPD did not specify which of the two Section 2.5 covenants it invoked. C&D further argues that SPD did not engage in a meaningful effort to negotiate the dispute during the 30-day window. But SPD's response letter

was provided within the 30-day window, stated the section of the settlement agreement relied on, and provided responses to a number of specific criticisms listed in C&D's letter. And aside from this letter, C&D offers no other evidence of SPD's failure to comply in good faith with Section 2.7. Thus, there is insufficient evidence to find it more likely than not that SPD breached Section 2.7(ii) of the agreement.

Second, C&D argues that SPD invoked Section 2.5, and thus forced C&D to engage in arbitration before bringing suit, without a good-faith basis for doing so.[23] Section 2.5 provides that C&D

> hereby grants SPD . . . a covenant-not-to-challenge, worldwide: (1) any Advertising Claim for [the Weeks Estimator] on the ground that it is ineffective at . . . (B) estimating the range of number of weeks (*e.g.*, 1-2 weeks, 2-3 weeks or 3+ weeks) since ovulation for which it was cleared by the FDA or the range of number of weeks since commencement of pregnancy for which it was cleared by the FDA if the FDA actually clears the product for the intended use of estimating the number of weeks from the commencement of pregnancy . . . provided that FDA did not prohibit SPD from making that claim and the claim clearly indicates whether it relates to the accuracy of the pregnancy test function or the accuracy of the weeks estimator function.

PTX 33 at 6. But in its post-trial briefing, SPD argues that it "viewed C&D as challenging the Product's effectiveness at 'estimating the range of number of weeks . . . since ovulation,'" and that "SPD justifiably and in good faith relied upon [this] *different* covenant in an attempt to bar C&D's claims." Dkt. No. 371 at 32 n.18. The only evidence C&D provides to contradict SPD's explanation is the Settlement Agreement, SPD's communications with the FDA, and correspondence between SPD and C&D leading up to the initial arbitration. But C&D's initial letter to SPD did not specify why its challenge to the Weeks Estimator's advertising was permitted under Section 2.5, and, moreover, C&D's letter references certain advertising messages discussing ovulation, PTX 34. Similarly, SPD's response letter does not specify which of the two Section 2.5 covenants it relied upon. PTX 35. In fact, based on the correspondence

[23] Much of the background and ultimate resolution of the arbitration is summarized in the Court's Memorandum & Order dated October 28, 2014, which denied SPD's motion *in limine* to limit the scope of the case to the pieces of advertising attached to C&D's Complaint. *Church & Dwight II*, 2014 U.S. Dist. LEXIS 158551.

that C&D provides, it appears that the earliest point at which C&D specified which Section 2.5 covenant provided the basis for its challenge was in October 17, 2013, which was after C&D had commenced arbitration against SPD. PTX 40; PTX 38. Based on this correspondence, it could be that these two parties were ships passing in the night, failing to understand which of the Section 2.5 covenants was at issue. In addition, C&D had the availability to call witnesses to augment or clarify this limited documentary record, but it failed to do so. Therefore, the Court concludes that there is not enough evidence to find it more likely than not that SPD lacked a good-faith basis for invoking Section 2.5 and forcing C&D to commence arbitration.

Third, C&D argues that SPD breached the implied covenant of good faith and fair dealing by invoking the covenant requiring arbitration for certain claims. But this good faith and fair dealing argument substantially overlaps with the second breach of contract argument noted above. Because C&D pleads a breach of contract claim on the same facts, it cannot bring a separate claim for breach of the implied duty of good faith and fair dealing.

Therefore, because there is an absence of evidence from which the Court could find that SPD breached the parties' Settlement Agreement, C&D's breach of contract claim fails.

IV. CONCLUSION

For the reasons provided above, the Court concludes that (1) SPD engaged in false advertising in violation of the Lanham Act; (2) SPD engaged in intentional deception of an egregious nature; (3) C&D is entitled to a permanent injunction; (4) SPD engaged in false advertising in violation of New York State law; and (5) C&D failed to prove that SPD breached the parties' prior settlement agreement.

In accordance with this Opinion and Order, the parties shall submit a proposed permanent injunction order no later than three weeks from the date of this Opinion and Order. If the parties are unable to reach an agreement, C&D shall submit a proposed permanent injunction order and the parties shall submit letters no longer than three pages in length setting forth their respective positions regarding the wording of the permanent injunction order.

In addition, no later than three weeks from the date of this Opinion and Order, the parties shall also submit a proposal for how to proceed with the damages phase of this case.

This resolves Dkt. Nos. 254, 265, 267, 269, 271, 273.

SO ORDERED.

Dated: July 1, 2015
New York, New York

ALISON J. NATHAN
United States District Judge

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC.,

Plaintiff,

–v–

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

Defendant.

14-CV-585 (AJN)

PERMANENT INJUNCTION ORDER

ALISON J. NATHAN, District Judge:

WHEREAS, by Opinion and Order dated July 1, 2015 (Dkt No. 397) ("July 1 Opinion"), the Court determined, *inter alia*, that defendant SPD Swiss Precision Diagnostics ("SPD") engaged in false advertising under the Lanham Act and that plaintiff Church and Dwight Co., Inc. (C&D) is entitled to a permanent injunction (July 1 Opinion at 1);

WHEREAS the Court has reviewed the subsequent submissions of the parties concerning the proposed wording for a permanent injunction order as directed in the July 1 Opinion (at 50-51);

NOW, THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

1. SPD and its officers, agents, servants, employees, representatives, parent companies, owners, subsidiaries, and affiliates (the "SPD Parties") are permanently enjoined from stating, implying, depicting, or otherwise communicating in any advertising or promotional materials or activity in the United States for the product currently known as the Clearblue Advanced Pregnancy Test with Weeks Estimator ("Product"), including but not limited to the advertising referred to in Paragraph 2 below, that the Product provides an estimate of weeks pregnant that is the same as a doctor's estimate of weeks pregnant.

2. Without in any way limiting the generality of the restraint set forth in the foregoing paragraph:

a. The SPD Parties are permanently enjoined from disseminating, distributing, broadcasting, or otherwise communicating in any way in the United States all of the advertising for the Product described in pages 12-19 of the July 1 Opinion (including the Internet-Only Commercial).

b. To the extent that any packaging, advertising or promotional materials for the Product promote the "weeks estimating" feature of the Product, such packaging, advertising or promotional material shall contain or include the following statement: "This product detects pregnancy and estimates weeks since ovulation. The estimate of weeks since ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of the last menstrual period" (the "Clarification Statement"). The Clarification statement shall be (i) in a font size at least 50% as large as the most prominent of the elements of any such advertising or promotional material promoting the "Weeks Estimator" feature of the Product, and (ii) immediately adjacent to the most prominent element(s) of the advertising or promotional material promoting the "Weeks Estimator" feature of the Product. Further, in the case of television or internet advertising, the Clarification Statement shall (i) be visible for at least as long as the elements of any such advertising promoting the "Weeks Estimator" feature of the Product and (ii) for audio advertising, be spoken in a clear and easily understandable manner.

c. Notwithstanding and without in any way limiting the generality of the foregoing, the SPD parties are permanently enjoined from disseminating, distributing, broadcasting, or otherwise communicating in any way advertising or promotional materials for the Product in the United States which contain or include (i) the words "weeks pregnant," "weeks along," "how far along," or materially similar words or phrases; (ii) images of any of the Product's digital results windows that contain the word "pregnant" with

numbers and/or the word "weeks"; or (iii) an image of a caduceus. Additionally, SPD shall not use the words "Weeks Estimator" in the Product's name unless it is modified within the name itself to make clear that it estimates weeks since ovulation only.

3. SPD shall cause to be removed from all retail and other points of sale (e.g. e-commerce websites) the Launch Package (as described in the July 1 Opinion) and the Revised Package (as described in the July 1 Opinion). Removal shall begin immediately upon entry of this Order and be completed by no later than 45 days from the day on which this Order is entered. During this period, SPD shall seek the necessary approval for its new packaging from the U.S. Food & Drug Administration ("FDA"). Failure to receive FDA approval for new packaging does not absolve SPD of its obligation to complete the recall of the existing Product within 45 days.

4. SPD shall, no later than 7 days from the day on which this Order is entered, deliver to all retailers, e-commerce websites, brokers, distributors, dealers, wholesalers, importers, and other non-consumer purchasers of the Product a written notice enclosing this Permanent Injunction Order addressed to each recipient's principal buyer (or a person holding an equivalent position) stating as follows:

"To: Our Valued Customers

Subject: Clearblue Advanced Pregnancy Test with Weeks Estimator

In January 2014, Church & Dwight filed a civil suit against SPD Swiss Precision Diagnostics GmbH, manufacturer of Clearblue®, alleging false and misleading advertising. On July 1, 2015, the United States District Court for the Southern District of New York ruled in favor of Church & Dwight and has issued the enclosed permanent injunction with respect to the Clearblue® Advanced Pregnancy Test with Weeks Estimator, enjoining previous advertising for the Product.

The Clearblue® Advanced Pregnancy Test with Weeks Estimator detects pregnancy and estimates weeks since ovulation. The Product's estimate of weeks since

ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of last menstrual period and ultrasound results.

The Court has ordered that the existing packaging for the Product be recalled. However, the Court found no issue with the safety of the Product itself, which was and remains cleared by the FDA. A copy of the Court's findings can be found at [URL for link to the opinion]. Should you have any questions about how the Clearblue® Advanced Pregnancy Test with Weeks Estimator results compare to a Doctor's estimate, please do not hesitate to contact us directly at: XXXXX@clearblue.com and the following telephone number: XXXXXXXXX."

a. Subject to FDA approval, SPD may include in the foregoing notice (the "Corrective Notice") additional explanation in written or chart form about how the Product's estimate compares to how a doctor would date a pregnancy.

b. The Corrective Notice shall be delivered in a manner calculated to ensure receipt by the appropriate recipient and shall not be accompanied by any other advertising or promotional materials.

5. SPD shall, for a period of one year from the date on which this Order is entered, make available copies of the Corrective Notice (with copies of the Permanent Injunction Order appended thereto) at all U.S. trade shows and professional meetings attended by SPD or any party representing SPD's interests. Copies of the Corrective Notice (with copies of the Permanent Injunction Order appended thereto) shall be placed in a prominent location at SPD's display or "booth" at each such trade show and professional meeting. The Corrective Notice shall not be accompanied by any other advertising or promotional materials.

6. Beginning no later than 7 days from the day on which this Order is entered and for a period of one year thereafter, SPD shall maintain a stand-alone page on the www.clearblueeasy.com website. The home page of the website and the Product web page shall include a prominent link, visible without scrolling, to the stand-alone page. The link shall be entitled "Corrective Notice: Clearblue® Advanced Pregnancy Test with Weeks Estimator." The

stand-alone page shall contain the following statement: "In January 2014, Church & Dwight filed a civil suit against SPD Swiss Precision Diagnostics GmbH, manufacturer of Clearblue®, alleging false and misleading advertising. On July 1, 2015, a federal court ruled in favor of Church & Dwight, enjoining previous advertising for the Product. The Clearblue® Advanced Pregnancy Test with Weeks Estimator detects pregnancy and estimates weeks since ovulation. The product's estimate of weeks since ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of the last menstrual period." The standalone page shall also provide a link to the text of the July 1 Opinion, with text stating "Click here to read a copy of the Court's decision."

7. As expeditiously as possible, SPD shall cause to be published in retailer circulars the following statement: "In January 2014, Church & Dwight filed a civil suit against SPD Swiss Precision Diagnostics GmbH, manufacturer of Clearblue®, alleging false and misleading advertising. On July 1, 2015, a federal court ruled in favor of Church & Dwight, enjoining previous advertising for the Product. The Clearblue® Advanced Pregnancy Test with Weeks Estimator detects pregnancy and estimates weeks since ovulation. The product's estimate of weeks since ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of the last menstrual period. A copy of the Court's Opinion including these findings can be found at [URL for link to the opinion]." This statement shall be published in the same circulars, in the same size, with the same frequency and for the same duration as SPD's circular advertising for the Product to date. The Clearblue logo shall be prominently displayed in each such circular placement.

8. As expeditiously as possible, SPD shall cause to be published internet banner advertising, prominently displaying the Clearblue logo, stating the following: "A federal court has determined that the maker of Clearblue® Advanced Pregnancy Test with Weeks Estimator engaged in false advertising. The product's estimate of weeks since ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of the

last menstrual period." The banner advertising shall run with the same frequency, for the same duration and on the same websites as SPD's banner advertising for the Product to date.

9. As expeditiously as possible, SPD shall cause to be published in *American Baby*, *Parents*, and *US Weekly* magazines a full-page advertisement stating the following: "In January 2014, Church & Dwight filed a civil suit against SPD Swiss Precision Diagnostics GmbH, manufacturer of Clearblue®, alleging false and misleading advertising. On July 1, 2015, a federal court ruled in favor of Church & Dwight. The Clearblue® Advanced Pregnancy Test with Weeks Estimator detects pregnancy and estimates weeks since ovulation. The product's estimate of weeks since ovulation is different from a doctor's estimate of how many weeks a woman is pregnant, which is based on the first day of the last menstrual period. A copy of the Court's Opinion including these findings can be found at [URL for link to the opinion]."

10. No later than 30 days from the day on which this Order is entered, SPD shall produce a video ("Explanatory Video") explaining the difference between the Product's estimate of weeks since ovulation and how a doctor dates pregnancy from last menstrual period, and make it prominently available: (a) on its web home page ready to play without scrolling down for a period of one year; (b) on the stand-alone page described in paragraph 6 for a period of one year; (c) as its first video on the landing page of the Clearblue YouTube channel for a period of six months; (d) as the first result for the next six months of any YouTube search with the words "Weeks Estimator"; and (e) on the Clearblue Facebook page which currently has approximately 475,000 fans. The following statement shall be prominently displayed on screen at the beginning of the Explanatory Video: "In July 2015, a federal court found the manufacturer of the Clearblue® Advanced Pregnancy Test with Weeks Estimator to have engaged in false advertising. For a copy of the Court's decision, please visit [URL for link to the opinion]."

11. Within 60 days of the day on which this Order is entered, SPD shall file with the court a sworn declaration setting forth in detail the manner in which it has complied with the provisions of this Order.

SO ORDERED.

Dated: August 26, 2015
New York, New York

ALISON J. NATHAN
United States District Judge

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co. Inc.,

Plaintiff,

-v-

SPD Swiss Precision Diagnostics, GmbH, *et al.*,

Defendants.

14 Civ. 00585 (AJN)

OPINION AND ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Church & Dwight ("C&D") has filed a Complaint against Defendant SPD Swiss Precision Diagnostics ("SPD") bringing claims for false advertising under the Lanham Act and New York General Business Law § 349.[1] In connection with this Complaint, C&D also filed a motion for a preliminary injunction. In response, SPD has opposed the preliminary injunction and has moved to dismiss the Complaint, arguing primarily that C&D cannot bring its claims because these are matters more properly resolved by the FDA. For the reasons explained below, the Court denies SPD's motion to dismiss and does not at this juncture reach the arguments raised by the preliminary injunction papers.

I. Legal Standard

When deciding a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept as true all well-pleaded facts and draw all reasonable inferences in the light most favorable to the non-moving party. *See Kassner v. 2nd Ave. Delicatessen, Inc.*, 496 F.3d 229, 237 (2d Cir. 2007). Although factual allegations are therefore afforded a presumption of truth, a court is "not bound to accept as true a legal

[1] C&D also brings a claim for breach of contract, the merits of which are not currently at issue.

conclusion couched as a factual allegation." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "To survive a motion to dismiss, the plaintiff's pleading must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

In addition to the allegations in the complaint, a court may consider documents attached as exhibits, incorporated by reference, or relied upon by the plaintiff in bringing suit, as well as any judicially noticeable matters. *See Halebian v. Berv*, 644 F.3d 122, 131 n.7 (2d Cir. 2011); *In re Harbinger Capital Partners Funds Investor Litig.*, No. 12 Civ. 1244 (AJN), 2013 WL 5441754, at *15 n.6 (S.D.N.Y. Sept. 30, 2013). "If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true." *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013) (quoting *Poindexter v. EMI Record Grp. Inc.*, No. 11 Civ. 559 (LTS), 2012 U.S. Dist. LEXIS 42174, at *6 (S.D.N.Y. Mar. 27, 2012)) (internal quotation marks omitted).

II. Background

A. C&D's Alleged False Advertising

1. C&D, SPD, and the Weeks Estimator Product

C&D and SPD are competitors in the market for home pregnancy test kits. Compl. ¶¶ 2, 15. Sometime around August 2013, SPD began marketing a new home pregnancy test kit, the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator" (the "Weeks Estimator"). Compl. ¶¶ 2, 17. Like other home pregnancy test kits, the Weeks Estimator was designed to tell a woman whether or not she is pregnant but also was designed to estimate the number of weeks

that had passed since the woman last ovulated. Compl. ¶ 17.

The crux of C&D's claims is that the Weeks Estimator cannot be used to provide an estimate of how long a woman has been pregnant. In particular, according to C&D, the medical profession does not measure pregnancy with reference to the time of ovulation—the time that an egg is released from the ovary—but rather measures it based on the "universally accepted convention" that pregnancy begins at the time of the woman's last menstrual period. Compl. ¶ 18. The last menstrual period occurs, on average, approximately two weeks before ovulation and, as a result, C&D alleges that doctors would determine the length of a woman's pregnancy differently using this standard than they would based on the date of ovulation. Compl. ¶ 18.

2. Allegedly False Advertising

C&D alleges that SPD has made false statements about the Weeks Estimator in a variety of different media.

a. The Weeks Estimator Box

First, C&D objects to the box containing the Weeks Estimator. In particular, C&D points to the product name—"Advanced Pregnancy Test With Weeks Estimator"—which is prominently displayed on the box, as well as rectangular graphics (representing the product's display window) on the box in which the words "Pregnant 1-2 Weeks," "Pregnant 2-3 Weeks," and "Pregnant 3+ Weeks" appear. Compl. ¶ 27. C&D also alleges that "[i]n violation of the FDA's directives, the indications for use statement does not appear in close proximity to the trade name or in similar font size or in bold font." Compl. ¶ 27. According to C&D "[t]he literal communication (or, at the very least, the necessary implication) of the Product packaging is that the Weeks Estimator can tell a woman how many weeks she has been pregnant -- specifically that she is 1-2 weeks pregnant, 2-3 weeks pregnant, or 3+ weeks pregnant." Compl. ¶ 29.

b. The Television Commercial

C&D also objects to a television commercial promoting the Weeks Estimator as promoting the same message: "that the Product can tell a woman how long she has been pregnant." Compl. ¶ 30. A woman tells a friend that she is pregnant, to which her friend exclaims "Really?!" Compl. ¶ 31. The woman holds up two fingers and says "two weeks." Compl. ¶ 31. After her friend asks whether she has already seen a doctor, the woman responds "Not yet," holds up the pregnancy test stick, and says "but I just took this new Clearblue test." Compl. ¶ 31. The scene moves to a close up of the test stick, with the Clearblue logo, and a display window with the word "Pregnant" and "1-2 Weeks" immediately below that word. Compl. ¶ 31. The pregnant woman then is heard to say "It's like two tests in one!" Compl. ¶ 31. The scene then changes to a graphic reflecting the three display windows noted above, while an announcer states "the new Clearblue pregnancy test also estimates how many weeks." Compl. ¶33. At the end of the commercial, the announcer concludes "Weeks Estimator. Only from Clearblue." Compl. ¶ 33.

c. SPD's Website

SPD also maintains a webpage promoting the Weeks Estimator product. Compl. ¶ 35. According to C&D, until its recent alteration that page referred to the Weeks Estimator as "the ONLY Pregnancy test that Estimates Weeks" next to a graphic of a test stick with "Pregnant 1-2 weeks" in the display window, with similar statements repeated farther down on the page. Compl. ¶ 36. The page also suggests that the Weeks Estimator "estimates the number of weeks," is "Like 2 Tests in 1," and notes that 78% of women surveyed believe it is important to know "how far along they are." Compl. ¶ 36.

Farther down, the page notes that the Weeks Estimator "estimate[s] how many weeks based on time since ovulation"—a phrase C&D claims is deceptive because time since ovulation is not the standard used to measure pregnancy. Compl. ¶ 37. At the bottom of the page, SPD includes the FDA's indications for use statement, including the required language quoted above. Compl. ¶ 38 & Ex. D.

d. Point of Purchase and Retail Advertising

C&D makes similar allegations that the point-of-purchase displays in which the Weeks Estimator is sold by retailers also are deceptive, in that each tray bears either the claim "First pregnancy test to estimate weeks" or "How far along are you?" Compl. ¶ 39. The trays do not contain the FDA's indications for use statement or disclose that the product measures time since ovulation. Compl. ¶ 40. C&D also challenges a web advertisement for the Weeks Estimator which states "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator. Is there a baby on board? How far along? Find out!" and other similar advertisements. Compl. ¶ 41.

e. The Press Release

Finally, C&D also raises a different challenge to the Weeks Estimator based on a press release announcing the launch of the product. Specifically, that press release claimed that the product was "approximately 93 percent accurate in estimating the number of weeks based on time since ovulation." Compl. ¶ 44. According to C&D, this statement is false because SPD's own package insert states that "Agreement of Weeks Estimator results with clinical findings ranged widely from 45%-99%." Compl. ¶ 45.

B. The FDA Process

In response to the preliminary injunction motion, SPD submits significant documentary evidence of its discussions of the Weeks Estimator product with the FDA, and urges the Court to

take judicial notice of its communications with the FDA in resolving the motion to dismiss. C&D does not contest this evidence as to the preliminary injunction but contends the Court may not consider it for purposes of the motion to dismiss. To provide context for this evidence, the Court will first briefly turn to the scheme under which the FDA regulates medical devices such as pregnancy test kits before discussing the evidence and whether it is properly considered in resolving the motion to dismiss.

1. The 510(k) Process

The FDA has authority to regulate medical devices under the Medical Devices Amendments Act. *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). Under that statute, "each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness." *Id.* at 74 (citing 21 U.S.C. § 360c(a) (defining the three classes of device)). Class I devices include, for example, elastic bandages and are subject to the least stringent regulation; "such devices can be marketed without prior approval and are subject only to 'general controls' that cover all medical devices." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 108-109 (2d Cir. 2006) (citing § 360c(a)(1)(A)). Devices such as powered wheelchairs and infusion pumps—and, as important here, SPD's Weeks Estimator product—are Class II devices which can be marketed without advance approval but, in addition to the general controls applied to all medical devices, may be also subject to "special controls." *Id.* at 109 (noting that special controls include postmarket surveillance, patient registries, or other measures) (citing § 360c(a)(1)(B)); *see also* 21 C.F.R. § 862.1155 (2014) (providing that devices testing for human chorionic gonadotropin are Class II devices when intended for use in detecting pregnancy but are Class III devices when used for any other purpose). Class III devices are generally subject to the most stringent regulation, including in particular a requirement of "premarket approval" by the

FDA before they may be commercially distributed. *Yale-New Haven Hosp.*, 470 F.3d at 74.

Class II devices are subject to the requirements of 21 U.S.C. § 360(k), also known as the "§ 510(k) process." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-479 (1996); *see also* 21 C.F.R. § 807.81 (2014) (describing the circumstances requiring a premarket notification submission). Under the § 510(k) process, a party seeking to market a medical device is required to submit a "premarket notification" to the FDA. *Id.* This notification includes a description of the devices and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is "substantially equivalent" to a pre-existing device. *See* 21 C.F.R. § 807.92 (2014); *Rita Med. Sys. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 U.S. Dist. LEXIS 52366, at *7-9 (N.D. Cal. July 17, 2006); *see also* 21 U.S.C. § 360c(i) (defining "substantial equivalence"). If the FDA determines that the device is "substantially equivalent" to a pre-existing device, the device may be marketed without further regulatory analysis unless and until the FDA initiates proceedings with respect to the pre-existing device. *See Lohr*, 518 U.S. at 478-479; *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010). Unlike the more rigorous premarket approval process "510(k) clearance 'does not in any way denote official approval of the device.'" *PhotoMedex*, 601 F.3d at 925 n.3 (quoting 21 C.F.R. § 807.97).

2. The Clearance Letter

In approving the Weeks Estimator for marketing, the FDA issued a Clearance Letter. Specifically, the Clearance Letter stated that the FDA had "determined that there is a reasonable likelihood that [the Product] will be used for an intended use not identified in the proposed labeling and that such use could cause harm." Compl. ¶ 22 & Ex. A at 1; Feldman Decl. ¶ 7 & Ex. A. Although not specifically identifying off-label use as the FDA's concern, the letter

required that, in the package insert, the "Weeks Estimator results should not be expressed as 'weeks pregnant' and should only be explained as the number of weeks that may have passed since ovulation." Compl. Ex. A at 2. It likewise required a chart in the package insert from which women could interpret the results of the Weeks Estimator in terms of how a doctor might date the pregnancy. *Id.* This chart explained that the Weeks Estimator result was measured by time of ovulation and that a doctor would date the pregnancy roughly two weeks longer than the Weeks Estimator, and also explained that doctors dated pregnancy based on last menstrual period. *Id.*

The Clearance Letter also required that the Weeks Estimator's "indications for use" statement be "prominently displayed in all labeling, including pouch box and carton labels and instructions for use, in close proximity to the trade name, of a similar point size and in bold and shall be conveyed accurately—including any limitations—in all promotional materials." Compl. Ex. A at 3. The required statement included the following:

> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

Id. The Clearance Letter concluded by stating, among other things, that "FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." *Id.*

3. C&D's Post-Clearance FDA Communications

On March 21, 2014, the Court ordered that C&D produce documents to SPD comprising its communications with the FDA regarding SPD's Weeks Estimator. In connection with its reply to the motion to dismiss, SPD has submitted four such documents produced to it by C&D. (Supp. Request for Judicial Notice ("SRJN") Exs. A-D). Based on these documents, it appears that starting in October 2013, counsel for C&D communicated with the FDA raising before that body many of the same concerns it now brings in this litigation, particularly as to the Weeks Estimator labeling, the television advertisement, and the point-of-purchase advertising. SRJN Exs. A-D.

4. Request for Judicial Notice

The facts discussed above are derived from the allegations in the Complaint, the Clearance Letter attached as an exhibit to the Complaint, and C&D's communications with the FDA which C&D has conceded are properly before the Court on the motion to dismiss. MTD Hr'g Tr. 18:8-13, May 22, 2014.

In addition, in connection with the motion to dismiss, SPD urges that the Court take judicial notice that the FDA took certain actions and held certain positions with respect to the Weeks Estimator. In support, SPD submits copies of the FDA's Hold Letter as to the Weeks Estimator (Request for Judicial Notice ("RJN") Ex. B); certain correspondence between SPD and the FDA discussing issues raised in the Hold Letter (RJN Exs. D-H); SPD's minutes of a 2013 teleconference with the FDA and proposed mitigation plan submitted to the FDA (RJN Ex. I); and two FDA guidance documents (RJN Exs. A, C), as evidence of those actions and positions.

Courts may consider materials properly subject to judicial notice in deciding a motion to dismiss. *Kalyanaram v. Am. Ass'n of Univ. Professors at the N.Y. Inst. of Tech.*, 742 F.3d 42, 44

n.1 (2d Cir. 2014); *cf. Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (noting a case in which the court had stated in dicta that courts may consider facts subject to judicial notice in considering motions to dismiss, but stating that "a plaintiff's reliance on the terms and effect of a document in drafting the complaint is a necessary prerequisite to the court's consideration of the document on a dismissal motion; mere notice or possession is not enough") (citing *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991)).[2] Federal Rule of Evidence 201 provides that a court "may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." SPD apparently requests judicial notice under Rule 201(2), citing a handful of cases in which courts have taken notice of facts contained in agency communications. *See Massachusetts v. Westcott*, 431 U.S. 322, 323 n.2 (1977) ("The fact that respondent holds such a license has been ascertained from the records of the Merchant Vessel Documentation Division of the Coast Guard."); *Hein v. Capitan Grande Band of Diegueno Mission Indians*, 201 F.3d 1256, 1259 n.4 (9th Cir. 2000) ("Upon the Splinter Group's motion, we take judicial notice of the letter from the Gaming Commission to counsel for the Splinter Group which states that the Commission cannot act without a definitive determination by the Secretary."); *Jones v. Conagra Foods, Inc.*, 912 F. Supp. 2d 889, 900-01 & n.6 (N.D. Cal. 2012) (taking judicial notice of an FDA letter stating the agency's position that a product containing "naturally-derived citric acid" may be labeled "natural").

[2] There is some conflict between the quotation from *Chambers* in the above parenthetical and other opinions taking judicial notice of matters that do not appear to have been relied on in the drafting of a complaint. *See, e.g., N.J. Carpenters Health Fund v. Royal Bank of Scot. Group, PLC*, 709 F.3d 109, 126-27 & n.11 (2d Cir. 2013) (judicial notice of newspaper articles). Nevertheless, even if the Court does not adopt the broad view of *Chambers* advocated by Plaintiff that judicial notice is only proper where the plaintiff relied on the documents at issue when drafting the complaint, *Chambers* still supports the proposition that judicial notice is not proper if plaintiff could not even have known of or possessed the documents containing the facts to be noticed.

However, SPD's communications with the FDA are not public records of agency actions. Rather, the documents SPD submits in support of its request for judicial notice are internal documents that SPD held in confidence and, in fact, that SPD urged must remain confidential even during the course of this litigation. The Court has found no case in which judicial notice of facts contained in such documents has been held proper. *See United States v. Speakman*, 594 F.3d 1165, 1172 n.4 (10th Cir. 2010) (refusing to take judicial notice of an arbitration award because the arbitration organization was not a public agency); *FDIC v. Loudermilk*, No. 1:12-CV-4156-TWT, 2013 U.S. Dist. LEXIS 166924, at *5-7 (N.D. Ga. Nov. 22, 2013) (refusing to take judicial notice of favorable FDIC reports that were not public documents); *cf. Chambers*, 282 F.3d at 153. Moreover, the authenticity of these documents is not beyond dispute. Nor is their accuracy beyond reasonable question, a concern that is particularly acute as to the 2013 teleconference meeting minutes, a document prepared by SPD purporting to memorialize a telephone call. Even the documents embodying communications between SPD and the FDA are subject to interpretation such that discovery may illuminate their meaning. Resolving a pre-discovery dispositive motion by taking notice of potentially disputed facts contained in such documents would not be proper. For purposes of this motion to dismiss, then, the Court will not consider them.

III. Lanham Act Claims and FDCA Preclusion

SPD argues that the FDA, rather than this Court, is the proper body to resolve C&D's Lanham Act claims, citing a doctrine that courts commonly describe as "preclusion" of Lanham Act claims by the Food, Drug, and Cosmetic Act ("FDCA"). As one court has noted, this doctrine is not subject to a "bright-line" rule of decision. *Healthpoint, Ltd. v. Stratus Pharms.*, 273 F. Supp. 2d 769, 786-87 (W.D. Tex. 2001). The Court first briefly addresses the general

doctrine and origins of FDCA preclusion. The Court then turns to applying the doctrine to this case.

A. FDCA Preclusion Generally

The law surrounding the possible preclusion of a cause of action by the FDCA—in this case C&D's claim for a Lanham Act violation—arises out of a tension between attempting to respect the boundaries Congress has imposed on enforcement of the FDCA while still giving effect to other federal statutes.

On the one hand, the FDCA "imposes a comprehensive set of requirements upon medical devices." *PhotoMedex*, 601 F.3d at 924. And, importantly, although citizens may in some circumstances petition the FDA to take administrative action, it is the FDA that is charged with investigating potential violations of the FDCA and there is no private right of action to enforce the FDCA. *See id.* (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)); *see also POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175-76 (9th Cir. 2012), *cert. granted* 134 S. Ct. 895 (2014). As a result, courts have held that the FDCA may "preclude" claims that stray into the FDA's enforcement domain. *See, e.g.*, *POM Wonderful*, 679 F.3d at 1175-76; *PhotoMedex*, 601 F.3d at 924; *Stratus*, 273 F. Supp. 2d at 780-81.

On the other hand, concerns about giving full effect to federal statutes—statutes such as the Lanham Act—that provide for a private right of action have made courts wary of applying this approach too broadly. *See Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) ("Courts have instead struck a balance between the two, allowing breathing space for the Lanham Act, but at the same time not letting it be misused as a naked attempt to enforce the FDCA and its implementing regulations."). It is well recognized that, when faced with two conflicting federal statutes, courts endeavor, as much as possible, to give maximum

effect to both of them. *See J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l*, 534 U.S. 124, 143-44 (2001); *POM Wonderful*, 679 F.3d at 1175. Likewise, courts have suggested that the differing aims of the FDCA and the Lanham Act may counsel against preclusion. *See, e.g.*, *Ivax*, 459 F. Supp. 2d at 933-34. The Lanham Act is directed toward protecting commercial interests and preventing unfair competition that arises due to false advertising. *See id.* at 933. In contrast, the FDCA is generally not focused on the truth or falsity of advertising claims but is instead directed to ensuring that drugs and medical devices are safe, effective, and not misbranded. *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008); *Ivax*, 459 F. Supp. 2d at 933-34.

The Court turns briefly to C&D's reference at oral argument to the Supreme Court's recent decision in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1386 (2014), which, in the course of discussing the parties' arguments that the case presented an issue of "prudential standing," explained that courts have a virtually unflagging obligation to hear and decide cases within their jurisdiction. As the foregoing cases make clear, the doctrine of FDCA preclusion is grounded in a view that the lack of a private action to enforce the FDCA necessarily brings that statute into tension with the Lanham Act. As a result, courts have essentially limited the substantive scope of Lanham Act claims to alleviate this concern. Thus, FDCA preclusion is not concerned with the Court's "jurisdiction" or a prudential doctrine regarding when a court should decide a claim authorized by law, but is rather focused on an implied statutory limitation to the Lanham Act itself by virtue of its potential conflict, in some situations, with the FDCA. As a result, the Court does not find *Lexmark* particularly informative as applied to this case.

B. Principles of FDCA Preclusion and Application to C&D's Claims

Based on the Court's survey of precedent, the basic application of the doctrine of FDCA preclusion is that courts refuse to usurp the FDA's role in the enforcement of the FDCA and the FDA's authority under that statute. *See POM Wonderful*, 679 F.3d at 1176 ("*PhotoMedex* teaches that the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations."). Courts have explained that preclusion is required not only when a plaintiff "seeks to enforce directly the FDCA through the Lanham Act" but also when a plaintiff attempts to "maintain a Lanham Act claim [that] requires direct application or interpretation of the FDCA or FDA regulations." *Stratus*, 273 F. Supp. 2d at 786; *see also Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 U.S. Dist. LEXIS 2372, at *19 (D. Kan. Feb. 26, 1997) ("[A] plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. . . . Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA . . . .").

The Court's review of the numerous cases cited by the parties and its own independent research leads the Court to agree with other decisions that have remarked that this doctrine is not subject to a "bright-line" rule of decision. *See, e.g.*, *Stratus*, 273 F. Supp. 2d at 786-87. Further complicating the Court's decision is the lack of binding precedent—whether from the Supreme Court or the Second Circuit—that provides a rule of decision or general guidance for the Court in approaching this doctrine. In light of this void, the Court is confronted with an array of diverse fact patterns in numerous cases, none of them authoritative, in which courts have applied or

refused to apply preclusion. Firm rules arising from these cases are elusive, but the Court observes some broad trends that guide its inquiry.

The Court's starting point is to briefly review the statutory and regulatory structure pertinent to the Weeks Estimator. Starting with the statutory regime, the FDCA provides that a device may be misbranded based on, among other things, a misleading or false label, insufficiently conspicuous words or statements, and failure to provide adequate directions for use. *See* 21 U.S.C. § 352(a), (c), and (f). Moreover, the 510(k) process as a whole turns on determining the "substantial equivalence" of a device to a previously marketed predicate based on the fact that it has the "same intended use" as the predicate device. 21 U.S.C. § 360c(i)(1)(A); *see also* 21 C.F.R. § 807.92 (2014) (requiring, in a 510(k) submission, a statement of intended use). As particularly pertinent to this matter, the FDCA provides that in conducting this review the FDA may require a statement that "provides appropriate information regarding a use of the device not identified in the proposed labeling" if the FDA determines "(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (II) that such use could cause harm." 21 U.S.C. § 360c(i)(1)(E)(i).

Likewise, the FDA's regulatory scheme demonstrates that the FDA is responsible for controlling the marketing of medical devices with respect to their intended uses. For instance, 21 C.F.R. § 801.5 (2014), defining what constitutes "adequate directions for use" of a medical device, provides that such directions shall allow a layman to "use a device safely and for the purposes for which it is intended." *See also* 21 C.F.R. § 801.4 (2014) (defining "intended use"). It further specifies that directions may be "inadequate because . . . of . . . incorrect specification of . . . all conditions, purposes, or uses for which the device is intended, including conditions,

purposes or uses for which it is . . . suggested in its oral, written, printed or graphic advertising." § 801.5; *see also* 21 C.F.R. § 801.61 (2014). And 21 C.F.R. § 801.15 (2014) regulates the prominence of required label statements.

Finally, looking to the Clearance Letter, the FDA found that there was a reasonable likelihood that the device would be "used for an intended use not identified in the proposed labeling" and, as a result, imposed limitations on how SPD could market the device. Compl. Ex. A at 1. The FDA specifically provided that "[p]erformance of the Weeks Estimator should not be displayed" on the box labeling and that users should be directed to the package insert for more information on that point. Compl. Ex. A at 1. As to the package insert, the FDA set forth a number of requirements, including that the Weeks Estimator result "should not be expressed as 'weeks pregnant' and should be explained as the number of weeks . . . since ovulation," the form in which to describe the performance of the Weeks Estimator feature, and that doctors may date pregnancy differently. Compl. Ex. A at 2. It also required prominent display of the indications for use—which the FDA drafted and contain two paragraphs on how the Weeks Estimator features worked—in all labeling and in all promotional materials. Compl. Ex. A at 3.

In light of this structure, SPD's argument that C&D's claims involve the application of the FDA's regulatory regime is not wholly without force. The FDA has significant authority over the marketing of the Weeks Estimator, particularly as to its intended uses. As a result, the potential for overlap in adjudicating C&D's Lanham Act claims is not trivial, and there is an arguable view of these claims—a view urged by SPD—in which they simply ask the Court to apply the regulatory regime just discussed.

However, a close reading of C&D's Complaint reveals that its claims are not so simple and that resolving them need not involve the direct application of the FDA's regulations. In

particular, the focus of C&D's Lanham Act claims is that SPD is falsely marketing the Weeks Estimator as capable of estimating the duration of pregnancy, *i.e.*, that SPD is falsely claiming that the Weeks Estimator may be used for a purpose that, in fact, it cannot fulfill.[3] Although portions of C&D's Complaint suggest that its false advertising claim relies on the FDA's findings on this point, *see, e.g.*, Compl. ¶¶ 4-5, 20, 22-25, 34, 38, 40, 42, C&D argues that this was not its intention. *See, e.g.*, MTD Opp. at 11. In particular, in its opposition to the Motion to Dismiss, C&D describes the basis of its claim as follows:

> SPD's advertising *is false because (i) the Weeks Estimator cannot measure pregnancy duration*; instead it measures the length of time since ovulation . . . and (ii) if a woman used SPD's product to estimate pregnancy duration, she would get a very different result from what her doctor would tell her.

MTD Opp. at 11 (emphasis in original). Thus, according to C&D, its references to the FDA's determination that the Weeks Estimator does not measure the duration of pregnancy based on time of last menstruation is evidence that SPD's marketing of the product for this use is false, but C&D's claim would exist even in the absence of the FDA's determination. *Id.*

On this view of C&D's Complaint, its claims are directed at the simple factual falsity of SPD's marketing of the Weeks Estimator. In that case, the Court's task in adjudicating C&D's claims would be essentially two-fold: determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers. *See Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010) (noting the elements of a Lanham Act false advertising claim). Put in the concrete terms of this case, the Court would be required to decide (1) whether SPD's marketing conveyed to consumers that the Weeks Estimator measures the duration of pregnancy based on the medically

[3] The exception is C&D's Lanham Act claim based on SPD's representation about the 93% accuracy of the Weeks Estimator. This component of SPD's advertising has not been the focus of the parties' briefing, but the Court notes that essentially the same analysis as conducted below applies to this aspect of C&D's claims.

accepted standard (*i.e.*, date of last menstrual period) and (2) that this message is false or misleading.

Based on the current record, it does not appear that either task requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter. For example, to decide that the Weeks Estimator was falsely advertised in violation of the Lanham Act as capable of measuring pregnancy based on the standard applied by healthcare professionals, the Court need not look to the FDA's regulations governing labeling medical devices with their intended uses. Nor need the Court make a determination whether the Weeks Estimator is in compliance with the FDA's regulations or the restrictions imposed by the Clearance Letter. In this respect, C&D' claim is independent of the FDCA and FDA regulations and would exist even in their absence. *See Epogen & Aranesp*, 590 F. Supp. 2d at 1291-92; *Grove Fresh Distribs., Inc. v. Everfresh Juice Co.*, Nos. 89 C 1113 et al, 1989 U.S. Dist. LEXIS 14147, at *7-8 (N.D. Ill. Nov. 27, 1989) ("Striking all reference to the FDCA regulations leaves a still valid (if hard to prove) complaint."); *Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989) (finding that the claim at issue was not precluded because plaintiff did "not base its claim solely on the FDCA or FDA regulations. . . . Even without the FDA regulation defining 'orange juice from concentrate,' Grove Fresh could attempt to establish a violation of section 43(a). Grove Fresh would simply need to provide other evidence establishing the proper market definition of 'orange juice from concentrate'.").

This perspective that preclusion would not apply to C&D's Lanham Act claims is consistent with the Court's review of numerous cases applying this doctrine. *See Merck Eprova AG v. ProThera, Inc.*, No. 08 Civ. 35 (RMB) (JCF), 2010 U.S. Dist. LEXIS 142372, at *11-13 (S.D.N.Y. Oct. 20, 2010) (allowing a Lanham Act claim alleging that defendant misrepresented

that its product contained pure L-5-methyltetrahydrofolic acid because it did not assert a violation of an FDA regulation or the FDCA, but was merely claiming that the advertising was false under accepted scientific standards; references to the FDA approval process were only a source of evidence on this point); *Sciele Pharma, Inc. v. Brookstone Pharms., LLC*, No. 1:09-CV-3283-JEC, 2010 U.S. Dist. LEXIS 142408, at *14-17 (N.D. Ga. June 23, 2010) (accepting the plaintiff's argument that its claim that defendant falsely represented that certain vitamins contained "L-MTHF, when they actually contain D,L-MTHF" would be proved by reference to a well-established scientific standard, rather than by reference to any provision of the FDCA or FDA); *Epogen & Aranesp*, 590 F. Supp. 2d at 1291-92 (holding that FDCA preclusion did not bar claims that "allege[d] fraud not dependent on the FDCA's prohibition on off-label promotion," even if "the deceptive statements may have been made in order to promote off-label uses of EPO").

As to C&D's reference in its Complaint to the FDA's scientific findings, a number of courts have held that courts may consider the FDA's positions on a matter as evidence of falsity in considering a Lanham Act claim. *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 469 (D.N.J. 2009) ("[C]ourts have consistently held that the FDA's scientific findings are not only relevant, but entitled to significant deference.") (citations omitted); *Iams Co. v. Nutro Prods.*, No. C-3-00-566, 2004 U.S. Dist. LEXIS 31136, at *15 (S.D. Ohio July 17, 2004) ("The FDA's conclusion is obviously relevant to the controversy between the parties . . . ."); *Zeneca, Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, at *99-100 (S.D.N.Y. July 15, 1999) (explaining that FDA's position was not sufficient to prove a Lanham Act claim, but was "persuasive evidence" of the falsity of the advertising statements given the agency's expertise).

And courts have likewise been clear that the mere fact that the FDA regulates in an area does not inevitably lead to preclusion. *See, e.g.*, *Epogen & Aranesp*, 590 F. Supp. 2d at 1291; *Ivax*, 459 F. Supp. 2d at 932-944 ("So long as courts are not required to perform authoritative interpretation and direct application of FDA regulations, then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act.") (internal citations omitted). Indeed, were courts unable to look to agency expertise in this fashion or if the mere fact that an agency had regulatory authority in an area was sufficient to invoke preclusion, the doctrine of primary jurisdiction, discussed below, would be incoherent. The entire premise of that doctrine involves courts waiting to adjudicate claims that implicate issues within an administrative agency's expertise until the agency has had an opportunity to express its position. As a result, the mere facts that C&D's Complaint cites actions taken by the FDA and that the FDA has some authority to act in this area do not counsel in favor of applying preclusion.

Turning to the cases that SPD cites in favor of applying preclusion, the Court finds that the cases SPD relies on are distinguishable from the case at hand. For instance, this does not appear to be a case in which resolving C&D's claims would necessarily require the Court to apply an FDA regulation to test the veracity of the advertising at issue, as is the case in many of the decisions cited by SPD. *See, e.g.*, *PhotoMedex*, 601 F.3d at 921-22, 927-28 (explaining that "[t]esting the truth of PhotoMedex's claim would . . . require a court to usurp the FDA's prerogative to enforce the FDCA" because the question of whether the laser device at issue required an affirmative clearance by the FDA was contingent on a factual determination, one to be made by the FDA, as to whether the device was significantly modified from a previously

approved device); *PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (noting briefly, in addressing standing to sue, that the plaintiff's "dogged insistence that PDK's products are sold without proper FDA approval suggests . . . that Friedlander's true goal is to privately enforce alleged violations of the FDCA"); *Sandoz*, 902 F.2d at 230-31 (resolving Lanham Act claim that an ingredient on a product label was "inactive" was false because the ingredient would be considered "active" under 21 C.F.R. § 210.3(b)(7) would have required the Court to "determine preemptively how a federal administrative agency will interpret and enforce its own regulations") (citations omitted); *Stratus*, 273 F. Supp. 2d at 787 ("It is for the FDA to exercise its discretion to determine whether Accuzyme, Panafil White, Kovia and Ziox are on the market lawfully, whether it be because they are grandfathered or are exempt from the FDA pre-clearance process.")[4]; *Summit Tech. v. High-Line Med. Instruments*, Co., 933 F. Supp. 918, 934 (C.D. Cal. 1996) (finding claim focused on allegedly false representations regarding the legality of importing certain lasers precluded because "the FDA has not yet determined whether to take action against Hi-Line for its importation of used Summit lasers"); *Braintree Labs.*, 1997 U.S. Dist. LEXIS 2372, at *20-21. Here, C&D's claims appear to be premised simply on the alleged factual falsity of SPD's advertisement statements under prevailing scientific and medical standards. Therefore, the decisions just cited raised claims that are fundamentally distinguishable from C&D's claims.

Likewise, also distinguishable are those cases in which there existed an actual conflict between an FDA action or regulation and the plaintiff's claims. For instance, although the FDA has regulatory authority over the intended uses of medical devices, this case is unlike *POM*

[4] *Stratus* held precluded a number of claims on essentially this theory. *See* 273 F. Supp. 2d at 787-88 (finding precluded claims that implicated questions of "what federal law does or does not require for [the products] to be marketed legally"; whether new drug applications were required; whether a party complied with good manufacturing practice; whether a product required an FDA approval or rating; and other similar issues; and whether the products were "misbranded" or "adulterated" under the FDA's standards).

Wonderful, which is now pending before the Supreme Court, because the regulatory scheme governing the Weeks Estimator does not—in itself—provide a basis to conclude that the Weeks Estimator box, label, or advertising has been authorized by the FDA. *See POM Wonderful*, 679 F.3d at 1176-77 (holding that plaintiff's claim based on the name and label of the product was barred because FDA regulations authorized the name that Coca-Cola had chosen, such that "Pom's challenge to the name 'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading."). In other words, while the court in *POM Wonderful* was able to find that the FDA had essentially blessed the name and label of the juice product at issue by promulgating regulations that plainly authorized the name and label, the current record before the Court demonstrates merely a general prohibition against the misbranding of medical devices as to their intended uses. *See POM Wonderful*, 679 F.3d at 1176-77. In general terms, the same is true with respect to the other cases that SPD relies on in which there was such an existing and actual conflict. *Compare Rita Med. Sys.*, 2006 U.S. Dist. LEXIS 52366, at *8-11 (precluding claims based on an alleged misrepresentation that one of defendants' medical devices was "compatible" for use with the plaintiff's device because in the course of the 510(k) process, defendants described the device at issue as designed for use with the relevant devices manufactured by plaintiffs and FDA cleared the defendants' device for marketing; explaining that the court would not "unduly convert[ ] the Lanham Act claim into a review of an FDA action"), *Cytyc Corp. v. Neuromedical Sys.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (holding that "representations by Cytyc that comport substantively with statements approved as accurate by the FDA cannot supply the basis for NSI's claims") (citations omitted), *and Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-46

(S.D.N.Y. 1987) (dismissing Lanham Act claim targeting product's assertion that it provided "safe" pain relief because "the FDA expressly found that there was a need for uniformity in RS warnings on the labels of aspirin-containing products and expressly preempted all conflicting regulations" and had specifically inspected and approved the packaging at issue),[5] *with PhotoMedex*, 601 F.3d at 924-25 ("If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued . . . . "), *and In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, at *70-71 (N.D. Cal. Aug. 16, 2006).

In this case, no such conflict is apparent from the current record. Specifically, viewed in the light most favorable to C&D, the Clearance Letter—standing alone—does not demonstrate that the FDA has reviewed the Weeks Estimator box and labeling actually sold by SPD and determined it will not mislead consumers as to the capabilities of the Weeks Estimator. First, the Clearance Letter's statement that it should not be viewed as a determination that the Weeks Estimator complies with other requirements of the FDCA or other federal law cautions against such a finding without the benefit of the materials explaining what, precisely, was before the FDA. In short, the Court simply cannot determine, at this stage, the precise nature of any conclusions the FDA may have made as to the Weeks Estimator. Second, as C&D pointed out at

[5] SPD argues that *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, No. 95 Civ. 7011 (HB), 1996 U.S. Dist. LEXIS 7257 (S.D.N.Y. May 24, 1996), also follows this logic. It does not: in that case the court did not hold that it could not consider the truth of the advertising at issue without intruding on the FDA's domain; rather, it held that the alleged misrepresentations were not facially false or misleading. *SmithKline Beecham*, 1996 U.S. Dist. LEXIS 7257, at *40-42. Specifically, the challenged advertisement was not false because it merely claimed that, when used according to the product label, PEPCID AC must be administered an hour before the onset of expected heartburn whereas the label for TAGAMET HB provided for administration a half-hour before the onset of expected heartburn. *Id.* at *21 n.10, *40-42. The court did, however, suggest it would not substitute its "discretion for that of the FDA in approving package labelling for over-the-counter medications" by second-guessing the accuracy of those labels. *Id.* at *21 n.10, *41.

oral argument, the Clearance Letter requires that many of the disclosures about the Weeks Estimator's uses be included on the package insert, rather than the box. MTD Hr'g Tr. 30:8-20. As a result, it may be that the box—even if approved by the FDA when taken in conjunction with the package insert—is misleading to the consumer at the time of purchase due to the unavailability of the package insert at that time.[6] Moreover, on a related point, although the potential for conflict between the FDA's views and a hypothetical judgment for C&D in this case exists, particularly given the Clearance Letter's directive that "[p]erformance of the Weeks Estimator should not be displayed on your box labeling," this statement is ambiguous. Read in context with the FDA's surrounding concerns that the Weeks Estimator "will be used for an intended use not identified in the proposed labeling," the FDA's directive not to display "[p]erformance of the Weeks Estimator" could mean many things, including a directive that SPD remove specific product claims it had made in the proposed labeling. Finally, even assuming that the Clearance Letter reflected the FDA's approval of *some* package design by SPD as not misleading, nothing in the Clearance Letter demonstrates that the FDA, in fact, approved the box and labeling that SPD *actually* placed on the market. The Clearance Letter does not describe or attach copies of the box or labeling that (according to SPD) the FDA approved, and the Court therefore has no basis at this stage to accept SPD's claim that the Clearance Letter reflects approval of the materials that SPD has actually marketed and sold.[7]

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[6] Here, the different purposes of the FDCA and Lanham Act are thrown into stark contrast: from the perspective of the FDA, so long as the consumer is adequately informed about the use of the Weeks Estimator post purchase and does not misunderstand its results, the FDA's safety concerns are addressed. But from the perspective of a competitor concerned about the consumer's purchasing decision, at that stage the harm that the Lanham Act seeks to prevent will already have been accomplished if the consumer was misled into purchasing the Weeks Estimator with a mistaken belief as to its function.

[7] The same fundamental point applies all the more strongly to SPD's other advertising or promotional materials, as there is nothing to suggest that the FDA had viewed, let alone approved, any such promotional materials. Instead, the Clearance Letter simply imposes the general requirement that SPD's promotional materials for the Weeks Estimator must include the indications for use statements drafted by the FDA. Compl. Ex. A at 3. Viewed in the light most favorable to C&D, the Court cannot view this portion of the Clearance Letter as preemptive approval by

In sum, and recognizing that this is a doctrine that does not lend itself to a simple application, the Court concludes that the materials before the Court do not, at this time, warrant preclusion of C&D's claims. The Court notes, however, that the questions raised by this doctrine are often fact-intensive, and are frequently resolved after the pleadings stage. *See, e.g.*, *PhotoMedex*, 601 F.3d at 928 (addressing appeal grant of summary judgment); *Merck Eprova AG v. Gnosis S.P.A.*, No. 07 Civ. 5898 (RJS), 2011 U.S. Dist. LEXIS 30683, at *18-21 (S.D.N.Y. Mar. 17, 2011); *Iams*, 2004 U.S. Dist. LEXIS 31136, at *15. As a result, it may be that SPD is able to re-raise this argument at a later stage, if appropriate given the development of the proceedings.

IV. Primary Jurisdiction

SPD also contends that C&D's claims are subject to dismissal under the doctrine of "primary jurisdiction." Primary jurisdiction is "concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties" and with "maintaining uniformity in the regulation of an area entrusted to a federal agency," particularly by allowing administrative agencies the first opportunity to address issues in their expertise. *Ellis v. Tribune TV Co.*, 443 F.3d 71, 81-82 (2d Cir. 2006) (internal citations omitted). In particular, courts look to whether the claim requires resolution of issues that have been placed within the special competence of an administrative agency and courts in the Second Circuit focus on four factors in making this inquiry:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of

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the FDA of any advertisement for the Weeks Estimator—no matter how misleading that advertisement may be as to the product's capabilities—so long as it includes this indications for use statement. The Court cannot, at this time, find C&D's claims precluded due to a conflict with the FDA's position on such a thin basis.

> inconsistent rulings; and (4) whether a prior application to the agency has been made.

Id. at 81-83. Courts are also required to balance the advantages of applying the doctrine against the potential costs that may arise from delay and complications in administrative proceedings. *Id.* at 83 (citations omitted).[8]

Based on the facts before the Court in assessing the motion to dismiss, the Court concludes that the doctrine of primary jurisdiction does not counsel in favor of dismissing this action. First, it bears mention that primary jurisdiction is a doctrine of deferral, not dismissal—courts do not invoke this doctrine to wholly refrain from hearing a claim but rather merely to provide an agency the *first* chance to weigh in if the claim implicates matters within the agency's special competence. *See United States v. Philip Morris USA Inc.*, 686 F.3d 832, 837 (D.C. Cir. 2012) (explaining that primary jurisdiction involves "suspend[ing] the judicial process pending referral . . . to the administrative body for its views") (internal citations omitted); *Ellis*, 443 F.3d at 81 (primary jurisdiction allocates "initial decisionmaking responsibility"); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 60 (2d Cir. 2006) (primary jurisdiction allows courts to refer issues to an agency for "resolution in the first instance") (citations omitted); *Bernhardt v. Pfizer, Inc.*, Nos. 00 Civ. 4042 (LMM) et al, 2000 U.S. Dist. LEXIS 16963, at *5-6 (S.D.N.Y. Nov. 16, 2000) ("If a court finds that an administrative agency has primary jurisdiction over the claim, the court stays the matter and directs plaintiff to file a complaint with the agency.") (citations omitted); *In re Genentech, Inc.*, No. C-88-4038-DLJ, 1989 U.S. Dist. LEXIS 14819, at *2-4 (N.D. Cal. July 7, 1989).

It appears that the FDA has already provided its views as to the principal scientific

[8] This is a prudential doctrine, *see, e.g.*, *Imagenetix, Inc. v. Frutarom USA, Inc.*, No. 12CV2823-GPC(WMC), 2013 U.S. Dist. LEXIS 173193, at *9 (S.D. Cal. Dec. 9, 2013), but because it merely assigns to the agency the first opportunity to address an issue, the Court does not believe it implicates the same concerns as those raised in *Lexmark*.

question that this Court might refer to it: whether the Weeks Estimator can measure the duration of pregnancy based on the last menstrual cycle. The answer, according to the FDA, is no. Indeed, the materials before the Court suggest that the FDA has gone one step further and also provided its opinion on whether a measure of pregnancy based on date of ovulation is the standard most commonly applied by physicians. Again, the FDA's answer is no.

With this in mind, the Court's task is to assess the potential consumer confusion caused by the manner in which the Weeks Estimator has been marketed. Numerous courts have held that invoking the doctrine of primary jurisdiction is inappropriate in such contexts, as this task lies within the Court's core competence. *See, e.g.*, *Goldemberg v. Johnson & Johnson Consumer Cos.*, No. 13-cv-3073 (NSR), 2014 U.S. Dist. LEXIS 47180, at *16-17 (S.D.N.Y. Mar. 27, 2014); *In re Colgate-Palmolive Softsoap Antibacterial Hand Soap Mktg. & Sales Practices Litig.*, Nos. 12-md-2320-PB et al, 2013 U.S. Dist. LEXIS 37152, at *17 (D.N.H. Mar. 28, 2013); *Jovel v. I-Health, Inc.*, No. 12-CV-5614 (JG), 2013 U.S. Dist. LEXIS 139661, at *20-21 (E.D.N.Y. Sept. 27, 2013); *In re Frito-Lay N. Am., Inc.*, No. 12-MD-2413 (RRM)(RLM), 2013 U.S. Dist. LEXIS 123824, at *27 (E.D.N.Y. Aug. 29, 2013); *Karhu v. Vital Pharms., Inc.*, No. 13-60768-CIV-COHN/SELTZER, 2013 U.S. Dist. LEXIS 112613, at *11-12 (S.D. Fla. Aug. 9, 2013); *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG) (RML), 2010 U.S. Dist. LEXIS 73156, at *54 (E.D.N.Y. July 21, 2010). The Court has the agency's answer on the primary matter for which its technical expertise may be invoked, strongly suggesting primary jurisdiction is not applicable.

As to the second factor, based on the regulatory structure discussed above, it appears that the FDA has some discretion as to how SPD markets the Weeks Estimator as to its intended use, particularly as to the box and labeling. *Cf. Bernhardt*, 2000 U.S. Dist. LEXIS 16963, at *8-9

("The above review of the relevant regulatory scheme convinces this Court that whether the notice requested by plaintiffs is warranted is a decision that has been squarely placed within the FDA's informed expert discretion [to address labeling of drugs as part of the drug approval process]."). Again, however, based on the materials presently before the Court, it appears that the FDA has completed the 510(k) process as to the box and labeling, issuing the Clearance Letter imposing the limitations it believes are necessary.[9] As a result, the Court concludes that this factor does not favor applying the doctrine of primary jurisdiction.

The same holds true for the third factor, the danger of inconsistent rulings. The Clearance Letter ameliorates much of the danger that the Court might rule inconsistently with the FDA's requirements. Although, as the Court has suggested, this letter is not wholly unambiguous when viewed in the context of the limited materials before the Court on the motion to dismiss, it provides the Court with guidance as to the FDA's position on the proper packaging and labeling of the Weeks Estimator. This factor also does not favor applying the doctrine of primary jurisdiction. *Goldemberg*, 2014 U.S. Dist. LEXIS 47180, at *20 (no danger of inconsistent rulings because agency was not simultaneously contemplating the same issue).

As to the fourth factor, C&D has made an informal application to the FDA requesting that it review SPD's compliance with the Clearance Letter as to the product packaging, labeling, and certain other promotional materials. *See Ellis*, 443 F.3d at 89 (noting that a prior application to the agency will usually support applying the doctrine of primary jurisdiction). The FDA has responded that it will review C&D's request to determine the best course of action, but does not indicate that it intends to take action or provide a timeline for any such response. As a result, the

[9] Although, as the Court explained in discussing FDCA conflict preclusion, the materials before the Court at this stage are limited on this point and render the Clearance Letter somewhat ambiguous, this does not change the fact that, based on the materials properly considered at this point, it appears that the FDA has made its determination on this point.

Court has little information as to what delay might be attendant to waiting for the FDA to respond to C&D's request.

Weighing these considerations, the Court concludes that the doctrine of primary jurisdiction does not favor deferral to the FDA at this time. The Court notes, however, that the litigation is in an early stage and its determination on this matter is based merely on the allegations of the Complaint and associated materials. As a result, the Court's determination on this point should not be viewed as precluding SPD from raising this argument at a later stage.

V. State Law Claims

SPD argues that C&D's state law claims should be dismissed on the same rationale as the dismissal of the Lanham Act claims.[10] MTD at 19. C&D does not argue that its state law claims are not subject to dismissal on the same basis as the Lanham Act claims, but merely contends that its Lanham Act claims are not subject to dismissal. MTD Opp. at 10 n.8. Thus, to the extent that the Lanham Act claims are dismissed, it appears C&D has not argued a basis for maintaining its parallel state law claims.

VI. The Preliminary Injunction

Pursuant to the Court's discussions with the parties following the initial pretrial conference in this matter, the Court indicated that it intended to address the issues discussed above in the context of both SPD's motion to dismiss and C&D's preliminary injunction request. Based on oral argument, a number of factors have convinced the Court that the proper course, for now, is to decide these issues only in the context of the motion to dismiss, and turn to them again at the consolidated trial on the merits.

First, given the absence of controlling precedent, or even substantial guidance, on the

[10] SPD also argues the Court should not exercise supplemental jurisdiction over these claims, but as C&D points out, even absent the Lanham Act claims there appears to be diversity jurisdiction in this matter. Moreover, because C&D's Lanham Act claims survive the motion to dismiss, federal question jurisdiction also remains.

issue of FDCA preclusion in the Second Circuit, the Court concludes it would be prudent to await the Supreme Court's decision in *POM Wonderful* before attempting to make a further determination on this doctrine. Having reviewed that case and considered the parties positions at oral argument, the Court views it as likely that any decision in *POM Wonderful* will inform the Court's analysis and may set forth a controlling rule to be applied in this case. Second, at oral argument C&D stated its position that, in fact, there is no preliminary injunction pending in this matter due to consolidation of this motion with the expedited schedule for addressing the merits. MTD H'rg Tr. 4:13-16, 45:1-4. In light of this representation, the Court sees little utility in deciding a component of a motion that the movant now believes is no longer in effect. Finally, in a similar vein, when the Court inquired into whether it should reserve decision on the pending motions until after the Supreme Court issues its decision in *POM Wonderful*, although SPD requested an immediate decision on the motion to dismiss, C&D suggested that the Court should wait for that decision. MTD H'rg Tr. 44:11-15, 45:7-9. As a result of these developments at oral argument, the Court has reconsidered its approach and determined that the efficient course for this matter is to resolve, at this time, only the motion to dismiss.

VII. Conclusion

SPD's motion to dismiss is DENIED. C&D's motion for a preliminary injunction is moot by virtue of the consolidation of that motion with a trial on the merits in this case. This resolves docket numbers 19, 58, and 73.

Despite their submission of a letter on May 8, 2014, stating that they would provide proposed trial dates to the Court, the parties have not yet submitted any concrete proposed trial dates to the Court. The parties are directed to submit a letter no later than one week following the date of this order proposing mutually agreeable trial dates, as well as a proposed schedule for

the completion of discovery in this matter. If the parties fail to do so by that date, the Court will set a schedule without the parties' input and will expect the parties to conform their schedules to that set by the Court.

SO ORDERED.

Dated: June 3, 2014
New York, New York

ALISON J. NATHAN
United States District Judge

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co. Inc.,

Plaintiff,

–v–

SPD Swiss Precision Diagnostics, GmbH,

Defendant.

14-CV-585 (AJN)

MEMORANDUM AND ORDER

ALISON J. NATHAN, District Judge:

The present motion *in limine* asks the Court to decide whether the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, bars certain false advertising claims brought under the Lanham Act, 15 U.S.C. § 1125(a). More accurately, the question is whether the FDCA bars Lanham Act false advertising claims relating to medical devices if the Food and Drug Administration ("FDA") pre-approved the medical device's labeling. The Court answered this question in the negative at the motion to dismiss stage, but it indicated that a different result might be reached on a more fully developed record and after the Supreme Court's anticipated decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). *See Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14 Civ. 00585 (AJN), 2014 U.S. Dist. LEXIS 76752, at *21-43 (S.D.N.Y. June 3, 2014) ("*Church & Dwight I*"). Shortly thereafter, the Supreme Court rendered a decision in *POM Wonderful*, which only strengthens the Court's earlier analysis on this point. Therefore, Defendant Swiss Precision Diagnostics, GmbH ("SPD")'s motion *in limine* to bar Plaintiff Church & Dwight Co. Inc. ("C&D")'s Lanham Act claim is DENIED.

I. LEGAL STANDARD

Generally, "'[t]he purpose of a motion in limine is to allow the trial court to rule in advance of trial on the admissibility and relevance of certain forecasted evidence.'" *Great Earth*

Int'l Franchising Corp. v. Milks Dev., 311 F. Supp. 2d 419, 424 (S.D.N.Y. 2004) (quoting *United States v. Paredes*, 176 F. Supp. 2d 192, 193 (S.D.N.Y. 2001)). And "[w]hile 'dismissing claims is not the prototypical purpose of a motion in limine,' such motions have sometimes been addressed on the merits and have sometimes 'been construed as or converted into motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure or motions for summary judgment under Rule 56.'" *Id.* (quoting *Fournier v. McCann Erickson*, 242 F. Supp. 2d 318, 334-335 (S.D.N.Y. 2003)).

As noted, the issue raised in this motion *in limine* was first raised at the motion to dismiss stage, which coincided with a motion for a preliminary injunction that the Court consolidated with an expedited bench trial on liability. Although the motion to dismiss was denied, the Court informed the parties that it was prepared to reconsider its ruling on a more fully developed record. At a subsequent conference with the parties, SPD requested permission to raise the FDCA preclusion issue as a pre-trial motion and contended that briefing could be done on the basis of the record as it then existed. Status Conf. Tr. 12:10-19, Aug. 12, 2014. The Court made clear that it discouraged summary judgment motion practice in bench trials and, because it wished to avoid a "duplication of effort, coupled with the fact that [the Court was] not persuaded [the preclusion analysis] could be done fairly in advance of the close of discovery," Status Conf. Tr. 13:25-14:2, it would only permit SPD to brief the FDCA preclusion issue once the record on the issue was fully developed. The parties agreed. Hence, because the record on this issue is now fully developed and because any issues of fact are to be tried before the Court rather than a jury, the Court will address the merits of SPD's motion, rather than treat it as a motion to dismiss under Rule 12(b)(6) or for summary judgment under Rule 56. *Accord Fournier*, 242 F. Supp. 2d at 335 (deciding, "for purposes of efficiency," to address a motion *in limine* on the merits rather than as a motion to dismiss or for summary judgment).

II. BACKGROUND

The Court assumes familiarity with its Opinion and Order dated June 3, 2014, *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, but the Court will briefly summarize portions of that decision that are relevant to the present motion.

C&D and SPD are competitors in the global market for home pregnancy test kits. Around August 2013, SPD began producing and marketing a new home pregnancy test kit called the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator" (the "Weeks Estimator"). The Weeks Estimator is designed to tell a woman if she is pregnant, but it has the added feature of also estimating the number of weeks that have passed since the woman last ovulated. As the Court earlier explained, "[t]he crux of C&D's claims is that the Weeks Estimator cannot be used to provide an estimate of how long a woman has been pregnant." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *4. This is because, "according to C&D, the medical profession does not measure pregnancy with reference to the time of ovulation—the time that an egg is released from the ovary—but rather measures it based on the 'universally accepted convention' that pregnancy begins at the time of the woman's last menstrual period." *Id.* (quoting Compl. ¶ 18). Based on this distinction, C&D alleges that SPD made a number of false statements in its advertising campaign for the Weeks Estimator, which included, *inter alia*, the Weeks Estimator's product packaging, the Weeks Estimator's television commercial, SPD's website, point-of-purchase displays, and an SPD press release.[1] In short, C&D contends that SPD's advertising for the Weeks Estimator—indeed, the very name of the product itself—conveys the message that the Weeks Estimator can tell a woman how many weeks she has been pregnant and that this message is false or misleading.

SPD moved to dismiss C&D's Complaint and opposed C&D's motion for a preliminary injunction primarily by asserting a preclusion defense. That is, SPD argued that the FDCA

[1] Following a separate motion *in limine*, the Court rejected SPD's request to limit the scope of the case to these specific pieces of advertising as opposed to the advertising claims (i.e., messages or assertions) contained in these pieces of advertising. *See Church & Dwight Co. v. SPD Swiss Precision Diagnostics GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 158551, at *10 (S.D.N.Y. Oct. 28, 2014) ("*Church & Dwight II*").

precludes C&D's Lanham Act claim because the FDA subjected the Weeks Estimator's labeling to a rigorous pre-approval process before the product was launched. In support of its FDCA preclusion argument, SPD submitted documentary evidence of its discussions with the FDA regarding the Weeks Estimator. The Court declined to take judicial notice of most of these documents with respect to the motion to dismiss, and, because the preliminary injunction was consolidated with an expedited bench trial on liability, the Court did not consider the documents in reaching its earlier decision.[2]

A. The Court's Motion to Dismiss Opinion

FDCA preclusion is premised on the FDA's "authority to regulate medical devices under the Medical Devices Amendments Act." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *8-9 (citing *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006)). That statute establishes three tiers, or classes, of devices, each subject to an increasingly stringent level of regulatory control to ensure safety and effectiveness. *Id.*; *see also* 21 U.S.C. § 360c(a). As a Class II device, the Weeks Estimator is subject to 21 U.S.C. § 360(k), more commonly known as the "510(k) process." *Id.* at *10 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996)). The 510(k) process requires the party seeking to market the device to notify the FDA prior to marketing the device with "a description of the device and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is 'substantially equivalent' to a pre-existing device.'" *Id.* (citing 21 C.F.R. § 807.92 (2014); *Rita Med. Sys. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 U.S. Dist. LEXIS 52366, at *7-9 (N.D. Cal. July 17, 2006)); *see also* 21 U.S.C. § 360c(i) (defining "substantial equivalence").

The Court's June 2014 Opinion noted that, because the FDCA "imposes a comprehensive set of requirements upon medical devices," and because the FDCA contains no private right of action, "courts have held that the FDCA may 'preclude' some claims that stray into the FDA's

[2] The Court instead limited its analysis to the allegations in C&D's Complaint, the Clearance Letter that the FDA issued to SPD for the Weeks Estimator which was attached to C&D's Complaint, and C&D's communications with the FDA. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *14.

enforcement domain." *Id.* at *19 (citations and internal quotation marks omitted). "On the other hand, concerns about giving full effect to federal statutes—statutes such as the Lanham Act—that provide for a private right of action have made courts wary of applying this approach too broadly." *Id.* Combining these two lines of thinking and "[b]ased on the Court's survey of precedent," the Court concluded that "the basic application of the doctrine of FDCA preclusion is that courts refuse to usurp the FDA's role in the enforcement of the FDCA and the FDA's authority under that statute." *Id.* at *22. Synthesized further, "preclusion is required not only when a plaintiff 'seeks to enforce directly the FDCA through the Lanham Act' but also when a plaintiff attempts to 'maintain a Lanham Act claim [that] requires direct application or interpretation of the FDCA or FDA regulations.'" *Id.* (quoting *Healthpoint, Ltd. v. Stratus Pharms.*, 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001)).

The Court's June 2014 Opinion held that C&D's Lanham Act claim implicates neither branch of FDCA preclusion. Rather, C&D's Lanham Act claim requires the Court to conduct a limited two-step inquiry: "determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers." *Id.* at *28 (citing *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010)). The FDCA did not preclude the Court from conducting this inquiry because, "[b]ased on the [motion to dismiss] record, it [did] not appear that either task requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter." *Id.* at *29. "For example," the Court continued,

> to decide that the Weeks Estimator was falsely advertised in violation of the Lanham Act as capable of measuring pregnancy based on the standard applied by healthcare professionals, the Court need not look to the FDA's regulations governing labeling medical devices with their intended uses. Nor need the Court make a determination whether the Weeks Estimator is in compliance with the FDA's regulations or restrictions imposed by the Clearance Letter. In this respect, C&D's claim is independent of the FDCA and FDA regulations and would exist even in their absence.

Id. at *29.

Lingering in the background of this discussion was the Ninth Circuit's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012). That opinion had held, in essence, that Lanham Act claims might be precluded if the FDA had authorized the challenged name and label. The Court distinguished the Ninth Circuit's opinion from the facts available at the motion to dismiss stage by noting that the "regulatory scheme governing the Weeks Estimator does not—in itself—provide a basis to conclude that the Weeks Estimator box, label, or advertising has been authorized by the FDA." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *35-36. "In other words, while the Court in *Pom Wonderful* was able to find that the FDA had essentially blessed the name and label of the juice product at issue by promulgating regulations that plainly authorized the name and label, the [motion to dismiss record] demonstrate[d] merely a general prohibition against the misbranding of medical devices as to their intended uses." *Id.* at *36. Thus, because the Ninth Circuit's opinion suggested that FDA authorization might provide a basis for FDCA preclusion, and because the record was not developed enough to determine the extent to which the FDA had authorized the challenged labeling, the Court held that "it may be that SPD is able to re-raise this argument at a later stage, if appropriate given the development of the proceedings." *Id.* at *43. As noted, the Court later confirmed at a status conference with the parties, which was held after the Supreme Court reversed the Ninth Circuit's decision in *POM Wonderful*, that SPD would be permitted to re-raise the FDCA preclusion issue one final time following the close of discovery but prior to trial. *See* Status Conf. Tr. 9:1-10, 12:10-13:16, 14:3-7, 16:22-17:15.

B. FDA's Pre-Approval of the Weeks Estimator's Labeling

Consistent with this understanding, SPD submits the present motion *in limine* and attaches a number of exhibits documenting the FDA pre-approval process.[3] These exhibits reveal that, unlike the situation in *POM Wonderful* in which the challenged product labeling was merely consistent with existing FDA regulations, the Weeks Estimator's product packaging and

[3] In some instances, SPD did not actually attach the documents as an exhibit to the present motion, but instead referred the Court back to its earlier filings that the Court refused to consider in the context of the motion to dismiss.

at least one internet commercial (though not all of its advertising) were subject to extensive FDA pre-approval. SPD argues that the FDA's "involvement was so extensive as to constitute full control of the packaging even before its release." SPD Br. 17. C&D, in contrast, contends that the FDA merely "permitted" rather than "mandated" the Weeks Estimator's product packaging. C&D Br. 2. Based on the documentary support provided by both parties, a fairer characterization of the FDA's involvement lies somewhere in between these two poles.

In August 2012, for example, the FDA issued a "Hold Letter" with respect to SPD's 510(k) application because it had identified a concern with the Weeks Estimator: Women could misinterpret its results or use the product for unintended purposes, with potentially adverse health consequences. Specifically, the Hold Letter expresses the concern that the product's

> weeks indicator feature may provide misleading information to lay population of users and the Indications for Use and labeling of this device is currently inadequate to assure that the intended user (untrained lay users at home) will understand the output of this new feature and be able to interpret it safely. For example, the output of this test is not aligned with gestational aging done by healthcare professionals (i.e., it will under-estimate gestational age by an average of 2 weeks). . . . Provided you are able to adequately respond to all items in this hold letter and adequately address all review questions pertaining to this submission, we are considering a [substantial equivalence] with limitations decision for clearance of this submission. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Indications for Use and in your device's labeling if your device is cleared.

Gittins Decl. Ex. A. at 2 ("Hold Letter"). The Hold Letter then provides specific changes to the Weeks Estimator's Indications for Use and labeling. For example, the Hold Letter requests changing the Weeks Estimator's Indications for Use to state, *inter alia*:

> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that can not be substituted for a doctor's determination of gestational age.

Hold Letter 2. With respect to the product's labeling, the Hold Letter requests, among other things, that SPD remove the following statement from every area of the box: "*Also Tells You How Far Along You Are.*" Hold Letter 3. The Hold Letter also requests changing the name of

the product to the "Weeks Estimation Indicator" rather than "Conception Indicator," which was SPD's initial name for the product. Hold Letter 3. SPD pushed back and proposed "Weeks Estimator," which the FDA accepted, Hold Letter 3, but there is no indication that SPD proposed other alternatives to the product's name or that the FDA would have rejected something other than "Weeks Estimator." In subsequent communications with SPD concerning the Weeks Estimator's labeling, the FDA opined on other aspects of the product's packaging, including font size and the location of certain language on the box. *See* Gittins Decl. ¶ 30 & Ex. D.

As the Hold Letter indicates, the FDA requested these changes under Section 513(i)(1)(E) of the FDCA, which provides that "when determining that a device can be found substantially equivalent to a legally marketed device, the [FDA] may require a statement in labeling[4] that provides appropriate information regarding a use of the device not identified in the proposed labeling." 21 U.S.C. § 360c(i)(1)(E)(i). The resulting clearance from the FDA is known as "SE [substantial equivalence] with limitations." Gittins Decl. ¶¶ 23-26 & Ex. B. A finding of substantial equivalence means the device "has the same technological characteristics as the predicate device" or "has different technological characteristics and . . . is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device." § 360c(i)(1)(E)(ii)(III); *see also* § 360c(i)(1)(A).

On December 10, 2012, the FDA issued its Clearance Letter, which allowed SPD to begin marketing the Weeks Estimator. Compl. Ex. A. ("Clearance Letter"). The Clearance Letter is largely consistent with the restrictions noted in the Hold Letter, but it also notes, for example, that "Performance of the Weeks Estimator should not be displayed on your box labeling. Box labeling should instruct users to see the package insert for test instructions and for more information on the Weeks Estimator." Clearance Letter 1. The Clearance Letter further states that "a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling." Clearance Letter 3. Finally, the Clearance Letter also states that

[4] "Labeling" is defined elsewhere as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

"FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." Clearance Letter 3.

In October and November 2013, C&D wrote to the FDA asking it to take "corrective action" against SPD for alleged violations of the Clearance Letter's labeling restrictions. Knowles Decl. Ex. A, B. Those letters raise contentions that overlap with C&D's assertions in this action. The FDA then reached out to SPD regarding some of these issues, which led SPD to submit a "mitigation proposal" to make certain changes to its product labeling and nationally aired television commercial. Gittins Decl. ¶ 56 & Ex. Q; Vinti Decl. Ex. 11. The FDA's response to SPD's mitigation proposal again reveals the FDA accepting some but not all of SPD's suggestions. Vinti Decl. Ex. 11. For example, the FDA ordered SPD to cease airing the Weeks Estimator's nationally televised commercial by December 6, 2013 because the commercial "still does not convey the limitations of your Week[s] Estimator completely, nor does it clearly state that the device can only estimate weeks since ovulation (and not weeks of pregnancy) and therefore does not present a balanced and accurate description of your device to consumers." Vinti Decl. Ex. 11. The FDA subsequently approved a modified commercial for internet use only, which, *inter alia*, "display[s] the [Indications for Use] statement in its entirety, in text and against a blank screen with sufficient time to allow the statement to be read by the viewer." Gittins Decl. ¶¶ 65-66 & Exs. V-W.

III. DISCUSSION

There is no doubt that the FDA subjected the Weeks Estimator's labeling to an extensive pre-approval process. The only question that remains is whether such extensive pre-approval precludes C&D's Lanham Act claims. The Court concludes it does not. In reaching this conclusion, the Court first explains below why *POM Wonderful*'s reasoning applies with equal force to medical device labeling and why FDA pre-approval does not bar Lanham Act claims, a conclusion that is bolstered by related Supreme Court precedent from the field of pre-emption. The Court then briefly discusses the two post-*POM Wonderful* cases that are on point, neither of

which alters this Court's conclusion. Finally, the Court examines SPD's argument that C&D's Lanham Act claim still requires the Court to interpret, apply, or enforce the FDCA, a field of FDCA preclusion that *POM Wonderful* appears to have left untouched.

A. *POM Wonderful*'s Reasoning Applies with Equal Force Here

As a preliminary matter, the Court notes that although *POM Wonderful* involved food and beverage labeling, its reasoning applies with equal force to medical device labeling. To explain, foods, drugs, and cosmetics regulated by the FDA are subject to various levels of oversight depending on the nature of the product, as suggested by the three classes of regulatory oversight of medical devices discussed above. The product at issue in *POM Wonderful*, fruit juice, receives less oversight than certain medical devices and prescription drugs. *POM Wonderful*, 134 S. Ct. at 2235. Nonetheless, in *POM Wonderful*, Coca-Cola contended that the FDA promulgates very specific regulations governing the naming and labeling of fruit juices, and, because Coca-Cola must comply with those regulations, it argued that Lanham Act claims that challenge the naming or labeling of fruit juice must be precluded. The Supreme Court disagreed, of course, but indicated in its opinion that the issue before it pertained to food and beverage labeling. For example, the opinion's introductory summation states that "[t]here is no statutory text or established interpretive principle to support the contention that the FDCA precludes Lanham Act suits *like the one brought by POM in this case*. . . . Competitors, in their own interest, may bring Lanham Act claims like POM's *that challenge food and beverage labels* that are regulated by the FDCA." *Id.* at 2233 (emphasis added).

Nevertheless, the Supreme Court's reasoning was not limited to a specific area of the FDCA. Instead, much of the Supreme Court's analysis applies with equal force to the rest of the FDCA, including regulation of medical device labeling. To begin with, the Supreme Court's analysis focused on the two statutes as a whole, emphasizing that they serve different, but complementary, purposes. "The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers." *Id.* at 2234.

"The FDCA statutory regime," in contrast, "is designed primarily to protect the health and safety of the public at large." *Id.* In addition, the Lanham Act "relies in substantial part for its enforcement on private suits brought by injured competitors," while "[p]rivate parties may not bring enforcement suits" under the FDCA. *Id.* at 2235.

Despite these divergent purposes and enforcement mechanisms, the statutes occasionally overlap. For example, "[t]he FDCA prohibits the misbranding of food and drink," and "[a] food or drink is deemed misbranded if, *inter alia*, 'its labeling is false or misleading.'" *Id.* at 2234 (citing 21 U.S.C. § 343(a)). Recognizing this overlap, the Supreme Court turned to principles of statutory construction, but it declined to decide which of POM's and Coca-Cola's preferred maxims of construction to apply. *Id.* at 2237. Instead, it stated that "[e]ven assuming that Coca-Cola is correct that the Court's task is to reconcile or harmonize the statutes and not, as POM urges, to enforce both statutes in full unless there is a genuinely irreconcilable conflict, Coca-Cola is incorrect that the best way to harmonize the statutes is to bar POM's Lanham Act claim." *Id.* Harmonizing the statutes did not require barring Lanham Act claims for the simple reason that the statutes do not actually conflict with one another.

Most importantly, neither statute contains an express prohibition or limitation on enforcement of the other, which was "of special significance because the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946." *Id.* "If Congress had concluded, in light of experience, that Lanham Act suits could interfere with the FDCA, it might well have enacted a provision addressing the issue during these 70 years." *Id.* Such long co-existence was of even greater import to the Supreme Court in light of the fact that Congress enacted amendments to both statutes during this time, "including an amendment that added to the FDCA an express pre-emption provision with respect to state laws addressing food and beverage misbranding." *Id.* The Supreme Court found it "significant that the complex pre-emption provision distinguishes among different FDCA requirements." *Id.* at 2238. "By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend

the FDCA to preclude requirements arising from other sources." *Id.* (citing *Setser v. United States*, 566 U.S. __, __, 132 S. Ct. 1463, 182 L. Ed. 2d 455, 461-62 (2012)).

In short, the Supreme Court concluded, "[t]he Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose. Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* In addition, the respective remedies of the two statutes promote a more "fundamental" harmony:

> Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By serv[ing] a distinct compensatory function that may motivate injured persons to come forward, Lanham Act suits, to the extent they touch on the same subject matters as the FDCA, provide incentives for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.

Id. at 2238-39 (citations and internal quotation marks omitted).

These conclusions all apply with equal force to Lanham Act claims relating to medical devices. For example, the FDCA's regulation of medical devices, though not of the same vintage as other parts of the FDCA, has nonetheless co-existed with the Lanham Act for nearly 40 years. *See* Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976). Moreover, Congress amended the FDCA to include a pre-emption provision for medical devices that is substantially similar to the pre-emption provision for food labeling discussed in *POM Wonderful*. *Compare* 21 U.S.C. § 343-1 *with* 21 U.S.C. § 360k. Thus, as with the regulation of food and beverage labeling at issue in *POM Wonderful*, during nearly forty years of co-existence, Congress has chosen to pre-empt certain state laws concerning medical devices, while saying nothing about preclusion of federal statutes such as the Lanham Act. Finally, the

FDA's perspective and expertise as compared to the knowledge of day-to-day competitors is at least as limited with respect to medical devices as it is for food and beverage labeling. Thus, be it food or medical devices, "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation." *POM Wonderful*, 134 S. Ct. at 2238.

B. FDA Pre-Approval Does Not Bar Lanham Act Claims

On the whole, then, the Supreme Court reasoned that the Lanham Act and FDCA complement each other, and, as demonstrated above, this harmony does not depend on which aspect of the FDCA is at issue. SPD argues, however, that the Supreme Court's opinion carved out Lanham Act claims that challenge labeling the FDA has pre-approved because the opinion noted that "[u]nlike other types of labels regulated by the FDA, such as drug labels, *see* 21 U.S.C. § 355(d), it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures." *Id.* at 2239. SPD's argument would be more persuasive but for the Supreme Court's rejection of almost identical arguments in two separate cases.

First, the Supreme Court rejected the pre-approval argument in *POM Wonderful* itself. As amicus curiae, the Government argued "that a Lanham Act claim is precluded 'to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of [the] label.'" *Id.* at 2240 (quoting Br. for United States as *Amicus Curiae* 11). The Supreme Court countered that "[i]n addition to raising practical concerns about drawing a distinction between regulations that 'specifically . . . authorize' a course of conduct and those that merely tolerate that course, the flaw in the Government's intermediate position is the same as that in Coca-Cola's theory of the case." *Id.* The Government's and Coca-Cola's arguments were flawed because they "assume[] that the FDCA and its regulations are at least in some circumstances a ceiling on the regulation of food and beverage labeling. But, as discussed above, Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling." *Id.* Thus, because the FDCA does not act as a ceiling on the regulation of food and beverage labeling, FDA pre-approval is beside the point.

Second, the Supreme Court rejected an almost identical pre-approval argument in *Wyeth v. Levine*, 555 U.S. 555 (2009), which, although a pre-emption rather than a preclusion case, is on all fours with the facts here. Despite the difference in doctrines, "pre-emption . . . principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *Pom Wonderful*, 134 S. Ct. at 2236.

In *Wyeth*, a drug manufacturer similarly argued "that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Wyeth*, 555 U.S. at 573-74. Applying an analysis that is parallel to its reasoning in *POM Wonderful*, the Supreme Court disagreed. For example, the Supreme Court noted that Congress may "have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 574. It further commented that "when Congress enacted an express pre-emption provision for medical devices in 1976, it declined to enact such a provision for prescription drugs." *Id.* at 567 (citations omitted). As in *POM Wonderful*, Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. The Supreme Court in *Wyeth* also emphasized that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs . . . . State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Wyeth*, 555 U.S. at 578-79 (footnote omitted). This observation echoes the observation in *POM Wonderful* that the Lanham Act leverages the knowledge and financial incentives of market competitors to augment the FDA's limited resources and narrower perspective in the regulation of false and misleading food and beverage labels. *POM Wonderful*, 134 S. Ct. at 2238. Since the FDA's pre-approval of medical device

packaging is at least as rigorous as its pre-approval of drug labeling, *Wyeth*'s pre-emption analysis informs this Court's approach to FDCA preclusion of the Lanham Act.

Despite this consistent rejection of the pre-approval argument, SPD attempts to distinguish the present facts from those in *POM Wonderful*, which did not involve FDA pre-approval of any specific labeling, by noting that the FDA specifically approved *this* product's labeling. Although this fact is a point of distinction, it does not alter the flaw in the pre-approval argument, which is an assumption that the FDCA and its regulations are a ceiling on the regulation of medical device labeling. SPD also seeks to distinguish *POM Wonderful* by arguing that whether or not the FDCA acts as a ceiling on the regulation of medical device labeling, the FDA's Hold and Clearance Letters made clear that the FDA intended *its* approval of SPD's product packaging to be the final word on the issue. This argument similarly misses a key lesson from both *POM Wonderful* and *Wyeth*: It is for Congress, not the FDA, to determine whether the FDCA and its regulations are a ceiling on the regulation of medical devices. *See POM Wonderful*, 134 S. Ct. at 2241 ("An agency may not reorder federal statutory rights without congressional authorization."). Regardless, it is doubtful that the FDA would agree with the position that SPD ascribes to it. Notably, the FDA's Clearance Letter expressly advises SPD "that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." Clearance Letter 3. Nor is there any other indication in the FDA's correspondence that it intended its actions to preclude Lanham Act claims.

Finally, under a theory similar to the floor-and-ceiling argument, SPD contends that C&D's Lanham Act claim should be barred under *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), which held that an "action was barred because it directly conflicted with the agency's policy choice to encourage flexibility to foster innovation." *POM Wonderful*, 134 S. Ct. at 2241. But, as in *POM Wonderful*, SPD can point to no FDA actions "discuss[ing] or even cit[ing] the Lanham Act, and [SPD] cites no other statement in the [FDA's communications]

suggesting that the FDA considered the full scope of the interests the Lanham Act protects." *Id.* In short, "[t]his is not a case where a lawsuit is undermining an agency judgment, and in any event the FDA does not have authority to enforce the Lanham Act." *Id.*

In sum, the Court concludes that the FDA's pre-approval of the Weeks Estimator's labeling does not preclude C&D from bringing a Lanham Act claim for false advertising. Applying *POM Wonderful*, the Court will not "elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act" because "the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels." *Id.* at 2241.

C. Other Cases Interpreting *POM Wonderful*

As far as the Court is aware, only two opinions decided post-*POM Wonderful* are relevant to the question at hand—one is consistent with this Court's conclusion, while the other implicitly adopts SPD's argument, but without fully engaging the issue.

The first case, *Catheter Connections, Inc. v. Ivera Medical Corp.*, No. 2:14-CV-70-TC, 2014 U.S. Dist. LEXIS 98206 (D. Utah July 17, 2014), also addressed FDCA preclusion of Lanham Act claims involving medical devices. Like SPD, the defendants in that action argued that the plaintiff's "claims under the Lanham Act . . . are barred because medical device testing and regulatory approval are exclusively handled by the FDA under the FDCA." *Id.* at *7. The *Catheter Connections* court agreed that "[i]f the circumstances 'inherently require' court interpretation of the FDCA and implementing regulations, the area of inquiry is precluded." *Id.* at *13 (quoting *Cottrell, Ltd. v. Biotrol Int'l Inc.*, 191 F.3d 1248, 1256 (10th Cir. 1999)). But, under this reasoning, the court found that the only precluded claim was an assertion that the defendant "has not complied with FDCA Section 510(k)," *id.* at *16, which would require the court to decide in the first instance whether Section 510(k) clearance is required—a determination left exclusively to the FDA. The remainder of the false advertising claims were not barred because, "[f]or each of those, a determination of the issues raised by Catheter Connections would not require FDA expertise and would not require the court to interpret the FDCA or FDA regulations." *Id.* at *17-18. Instead, those claims focused on the "substance of

[defendant's] representations in the context of the medical device market and what drives buyers' purchasing decisions." *Id.* at *19. *Catheter Connections* is thus consistent with the Court's earlier Opinion at the motion to dismiss stage and its holding here.

The second case is *JHP Pharmaceuticals, LLC v. Hospira, Inc.*, No. CV 13-07460 DDP (JEMx), 2014 U.S. Dist. LEXIS 142797 (C.D. Cal. Oct. 7, 2014). On the one hand, that case similarly observed that "[t]he logical building blocks of [*POM Wonderful*'s] specific holding with regard to food and beverage labeling would seem to be equally applicable to food and beverage advertising, drug marketing, medical device labeling, cosmetic branding, or any other kind of marking or representation which would fall under both the Lanham Act and the FDCA, *unless* preclusion is required for some specific reason." *JHP Pharmaceuticals, LLC*, 2014 U.S. Dist. LEXIS 142797, at *13. But in a footnote, the court briefly commented that

> the Supreme Court suggested two such reasons in *Pom Wonderful*: the FDA may have pre-approved a particular labeling scheme, as in the labeling of FDA-approved drugs; or the agency may have authorized a menu of possible lawful choices for manufacturers, as was the case in *Geier*. (The common element, of course, is positive regulatory action in the matter by the FDA.).

Id. at *13 n.5. As extensively discussed above, the Court disagrees with the first half of this conclusion based on the Supreme Court's refusal to accept the Government's pre-approval argument in *POM Wonderful* and its refusal to pre-empt state tort claims in the face of a pre-approved drug label in *Wyeth*, neither of which are discussed in *JHP Pharmaceuticals*.[5]

D. C&D's Claim Does Not Seek to Enforce the FDCA

Although the Court is convinced that Lanham Act claims are not precluded merely because the FDA pre-approved a medical device's labeling, the Court agrees with the *Catheter Connections* court that *POM Wonderful* did not disturb the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA. That is, because the FDCA does not contain a private right of action, claims that require a court to interpret, apply, or enforce the FDCA remain precluded. *See Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at

[5] The analysis of *POM Wonderful* in *JHP Pharmaceuticals* is further discounted because the plaintiff's claim in that case failed for an alternative reason, so the court did not resolve this "thorny" issue. *Id.* at *28-29.

*21-22. But it is still the case that C&D's claims will only require the Court to "determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers." *Id.* at *28. Even in light of the more fully developed record, which reveals the extent of the FDA's pre-approval of the Week's Estimator's labeling, neither task "requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter." *Id.* at *29.[6]

Attempting to shoehorn C&D's claim into the category of precluded claims that usurp the FDA's role, SPD argues that C&D is challenging not just the Weeks Estimator's advertising, but the FDA's clearance of the product itself. For example, SPD argues that "C&D is attacking the Product itself as inherently misleading and unsafe. In other words, C&D is asking this Court to reverse the FDA clearance because, according to C&D, the Product is providing inherently misleading information to consumers." SPD Br. at 1. But C&D has made clear in its Complaint and throughout this litigation that it is challenging advertising that literally or implicitly conveys the message that the product does something it cannot—estimate the number of weeks a woman has been pregnant based on what C&D contends is universally accepted medical practice. "C&D does not seek to overturn [the] FDA's clearance of the Product for the intended use of (i) detecting whether or not a woman is pregnant and (ii) estimating how many weeks [have passed] since she last ovulated." C&D Br. at 1. Relatedly, SPD argues that C&D's challenge to the name of the product itself is a "direct assault" on the FDA's clearance of the product. But challenging the product's name is not the same as challenging the FDA's clearance of the product for its intended use. Moreover, although the FDA accepted the name "Weeks Estimator," the FDA did not indicate that SPD is prohibited from considering alternatives to the "Weeks Estimator," other than, perhaps, the already rejected name ("Conception Indicator").

[6] Portions of C&D's Complaint suggest that it might be attempting to enforce the FDCA, but C&D earlier clarified that this was not its intention and that "its references to the FDA's determination that the Weeks Estimator does not measure the duration of pregnancy based on time of last menstruation is evidence that SPD's marketing of the product for this use is false, but C&D's claim would exist even in the absence of the FDA's determination." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *28.

A more valid concern is that SPD might find itself stuck between a rock and a hard place, trying to honor the FDA's wishes while avoiding Lanham Act liability. The Court believes that this concern is lessened here for the same reason it was mitigated in *Wyeth*: A mere finding that a medical device is falsely advertised does not necessarily proscribe use of a device that the FDA has pre-approved or labeling that the FDA has required. In *Wyeth*, for example, the defendant drug manufacturer argued that a state jury's finding that its drug label failed to adequately warn of the dangers of a particular use of its drug (IV-push administration) was the equivalent of a proscription of that use, which the FDA had approved. *Wyeth*, 555 U.S. at 565. In response, the Supreme Court cited approvingly the Vermont Supreme Court's explanation that

> the jury verdict established only that Phenergan's warning was insufficient. It did not mandate a particular replacement warning, nor did it require contraindicating IV-push administration: "There may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating IV-push administration."

Id. (quoting *Levine v. Wyeth*, 183 Vt. 76, 93 n.2 (2006)). Similarly, a finding that a medical device is falsely advertised will not itself prohibit the use of a medical device that the FDA has approved or mandate any particular replacement labeling different from what the FDA has already approved as there may be any number of ways to advertise the product that do not mislead consumers and comply with FDA requirements. Indeed, *Wyeth* suggests an iterative process in which the manufacturer, which at all times "remains responsible for updating [its] labels," *id.* at 568, would "change its drug label based on safety information that becomes available after a drug's initial approval" with FDA input and approval if required, *id.* at 567. *See also id.* at 571 ("Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications."). The FDA's Clearance Letter similarly suggests that SPD may want or need to make changes to the Weeks Estimator's labeling, which would require FDA approval. Clearance Letter 3 ("[A] new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.").

"[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, [the Supreme Court would] not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571. Similarly, absent clear evidence that the FDA would not approve a change to the Weeks Estimator's labeling in response to concerns that it is misleading consumers, there is no reason to conclude that it would be impossible for SPD to comply with both the FDCA and the Lanham Act.[7]

IV. CONCLUSION

Therefore, because the FDCA and Lanham Act complement each other, and because FDA pre-approval of the Weeks Estimator's labeling does not preclude C&D from bringing a Lanham Act claim, SPD's motion *in limine* is DENIED. This resolves ECF No. 223.

SO ORDERED.

Dated: March 24, 2015
New York, New York

ALISON J. NATHAN
United States District Judge

[7] SPD makes much of the fact that the FDA requested SPD to make some changes to the product's packaging following C&D's complaints to the FDA in 2013. But there is still no reason to assume that, in the event SPD is found liable for false advertising under the Lanham Act, the FDA would prohibit SPD from making changes to its product packaging that would enable it to comply with both the Lanham Act and the FDCA.

STATUTORY AND REGULATORY PROVISIONS

Lanham Act

15 U.S.C. § 1125(a)

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

(2) As used in this subsection, the term "any person" includes any State, instrumentality of a State or employee of a State or instrumentality of a State acting in his or her official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this chapter in the same manner and to the same extent as any nongovernmental entity.

(3) In a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional.

Food, Drug, and Cosmetic Act

21 U.S.C. § 360c(a)(1)

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

> (A) Class I, general controls—
>
> > (i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j

of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, special controls—

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, premarket approval—

A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient

to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

21 U.S.C. § 360c(f)(1)(A)(i)-(ii)

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type[.]

21 U.S.C. § 360c(i)(1)(A)-(B)

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a

predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

21 U.S.C. § 360c(i)(1)(E)

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

21 U.S.C. § 360k

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 282(j)(1) of Title 42) shall be accompanied by the certification required under section 282(j)(5)(B) of such title. Such certification shall not be considered an element of such notification.

21 C.F.R. § 807.81

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b)(1) A premarket notification under this subpart is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(2) The appropriate FDA Center Director may determine that the submission and grant of a written request for an exception or alternative under § 801.128 or § 809.11 of this chapter satisfies the requirement in paragraph (a)(3) of this section.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of part 1002 of this chapter.

21 C.F.R. § 807.92

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."

(d) Any other information reasonably deemed necessary by the agency.